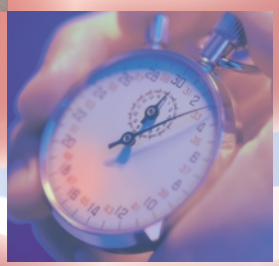
Launch Book
Roche *OPTI R*
Critical Care Analyzer

March 2001
For internal use only



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1 Introduction

Dear Colleagues,

Roche is proud to announce the availability of the new **Roche OPTI R Critical Care Analyzer**.
The **Launchbook**, which contains important marketing, strategic selling and technical product information is designed to maximize your sales and marketing activities for this product.

The **Roche OPTI R Critical Care Analyzer Launchbook** contains a **Table of Contents** that will guide you in locating information pertaining to specific topics such as Product Positioning, Competition, SWOT Analyses and Scientific Evidence, etc.

Our goal is to provide you with the tools that will allow you to demonstrate to your prospects and customers why Roche is the leader in the Hospital Point of Care market.

We are convinced that the superior technology and ease of use of the **Roche OPTI R Critical Care Analyzer** make this instrument ideally suited for the stat blood gas/electrolyte market.

With the availability of the **Roche OPTI R Analyzer**, Roche is able to provide a complete portfolio of products to meet the needs of our Hospital Point of Care customers.
The portability and simplicity of **Roche OPTI R** analyzers make them ideal for Hospital Point of Care solutions such as those arising in operating theatres, intensive care units and emergency.
The reusable cassettes, which can be used up to 25 times, further simplify the measurement process as they do not need to be changed during critical situations, e.g. operation.

Through the introduction of the **Roche OPTI R** system Roche is now able to fill the gap of the "mid range" sample throughput of 3-12 patient samples per day with a competitive parameter panel, "simple-maintenance" design and reasonable cost per test.

Upon reviewing the Launchbook, if you have any additional questions regarding this product or information, please contact us at your convenience.

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With best regards ... Your Roche OPTI R Team

2 The Message

2.1 The Time Saving Solution for Multiple Situations

Roche OPTI R Critical Care Analyzer

- Offers **time-saving** flexibility e.g. in the OR, ICU and other critical care environments
- **Rapid** on-site testing
- **Always Ready** for immediate testing – no warm-up time required
- One **reusable, multi-sensor cassette**, providing multiple patient results (up to 25) eliminates switching in the middle of critical procedures and reduces costs and operator handling
- One **reusable, multi-sensor cassette** enables to measure the combination of blood gas/electrolyte parameters and tHb/$S0_2$
  (Parameters: pH, $P0_2$, $PC0_2$, tHb, $S0_2$, Na^+, K^+, Ca^{++})
- Offers **convenience and safety** due to the SnapPak which contains the wash/calibration solution required for all parameters and includes a sealed waste container
- **Portability** and **simple handling**
- **Accuracy** that compares to our benchtop systems

3 Executive Summary

3.1 Intended Use

The Roche OPTI R Critical Care Analyzer is a powerful tool designed to help you quickly, accurately, and efficiently conduct basic testing of pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb and SO_2 in samples of whole blood; and pH, Na^+, K^+, and Ca^{++} in serum and plasma in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

The Roche OPTI R Critical Care Analyzer – the cornerstone of the system – is a **small portable** instrument that minimises dependence on the central laboratory facility when rapid results are needed. The total weight is less than 5,5 kg (eleven pounds), which makes it easy to transport wherever it is needed. It can be operated either by its on-board rechargeable battery for up to eight hours or directly from A/C power.

The Roche OPTI R Analyzer is a nearly maintenance free device, using solid state multi-use optical fluorescence sensor cassettes and an on-board OPTI R SnapPak. The sensor cassettes can be stored at room temperature. Each sensor cassette contains two (2) barcode labels, which contain information such as expiration date, lot number and calibration information. The OPTI R Analyzer is ideally suited for any POCT areas including the following:

- Operating Room
- Emergency Department
- Stat Labs
- Main Laboratory (backup for benchtop analyzers)

3.2 Importance of …..

3.2.1 pH

The pH value of the blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

a) primary bicarbonate deficit - metabolic acidosis
b) primary bicarbonate excess - metabolic alkalosis
c) primary hypoventilation - respiratory acidosis
d) primary hyperventilation - respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO_2, due to hyperventilation.

A decreased pH value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H^+ ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic; as the result of obstructive or restrictive respiratory diseases.

Reference Interval[1]

pH

Laboratory normal ranges for arterial carbon dioxide tension are well documented and widely accepted:

Parameter	Mean	2 SD
pH	7.40	7.35 – 7.45

3.2.2 *P*CO_2

The *P*CO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide, a by-product of metabolism. A *P*CO_2 value below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial *P*CO_2 above the normal range is termed respiratory acidosis and indicates *hypercapnia*, a sign of ventilatory hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

Reference Interval

PCO_2

Laboratory normal ranges for arterial carbon dioxide tension are well documented and widely accepted:

Parameter	Mean	2 SD
PCO_2 (mmHg)	40	35 – 45

3.2.3 PO_2

The *P*O_2 value of arterial blood is used to assess how well the body is able to absorb oxygen in the lungs. Values below the normal arterial *P*O_2 (*arterial hypoxemia*) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decrease in cardiac output, increased oxygen demand, anatomical heart defect, low inspired O_2 content). Generally, O_2 levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal

[1] Shapiro BA, Harrison RA, Cane RD, Kozlowski-Templin R.Clinical Application of Blood Gases, 4th ed., (Chicago: Year Book Medical Publishers, Inc.,1991) p 79-83

haemoglobin concentrations, 80 - 100 mmHg, PO_2 provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Reference Interval

Arterial oxygen tension, PO_2 is dependent upon the inspired oxygen tension, as well as various physiologic variables, and the administration of oxygen is common in the treatment of patients in need of blood gas analysis. Hypoxemia is defined as an arterial PO_2 below an acceptable range while breathing room air, with about 21% oxygen, at sea level. Increasing altitudes above sea level will produce lower inspired oxygen tensions and therefore, lower arterial PO_2 values.

Accepted arterial oxygen tension at sea level, while breathing room air:

PO_2[2]

Adult and Child		
Normal	97 mmHg	
Acceptable range	> 80	mmHg
Hypoxemia	< 80	mmHg
New-born		
Acceptable range	40 - 70	mm Hg
Aged		
Acceptable range		
60 years old	> 80	mmHg
70 years old	> 70	mmHg
80 years old	> 60	mmHg
90 years old	> 50	mmHg

Each laboratory should establish its own reference interval for pH, PCO_2 and PO_2 as performed on the Roche - OPTI R Analyzer as factors such as altitude can affect such measurements.

3.2.4 Sodium

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium **intake, sodium** losses due to vomiting or diarrhoea with adequate water and inadequate salt replacement, diuretics

[2] Kaplan LA, Pesce AJ. Clinical Chemistry: Theory, analysis and correlation, 2nd Ed. (St.Louis: C.V.Mosby Co. 1989) p 590-591.

abuse, or salt-losing nephropathy; osmotic diuresis, metabolic **acidosis, adrenocortical** insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic **failure and** hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhoea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's **syndrome, inadequate** water intake because of coma or hypothalamic **diseases, dehydration or excessive** saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhoea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

Reference Interval

***Sodium*[3]**

sample type	range, mmol/L
whole blood, serum and plasma	
premature new-born @ 48 hr.	128-148
full term, new-born	133-146
infant	139-146
child	138-145
thereafter	136-145
cerebrospinal fluid	136-150

3.2.5 Potassium

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K^+/H^+ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhoea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

[3] Siggard-anderson O, Durst RA, Maas AHJ.IFCC/IUPAC approved recommendation (1984) on physicochemical quantities and units in clinical chemistry. *J clin Chem Clin Biochem.* 25:369-391, 1987.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhoea, hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

Reference Interval

Potassium[3]

sample type	range, mmol/L
whole blood, serum and plasma	
new-born	3.7-5.9
infant	4.1-5.3
child	3.4-4.7
thereafter	3.5-5.1
cerebrospinal fluid	0.70 plasma level fraction; 2.5-3.2, rises with plasma hyperosmolality

3.2.6 Ionized Calcium

Calcium in blood is distributed as free calcium ions (50%); bound to protein, mostly **albumin (40%), and** 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI R Analyzer measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, hypercalcemia, may be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.

Patients with renal disease caused by glomerular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method of accurately monitoring calcium status in renal disease.

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

Reference Interval

Ionized Calcium[3]

sample type	range, mmol/L
whole blood, (Hep)	
adult	1.12-1.32
plasma (Hep)	
adult	1.03-1.23
serum	
adult, >18 yr	1.16-1.32
1 - 18 yr	1.20-1.38

3.2.7 Total Haemoglobin concentration (tHb)

The haemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram of haemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid. Decreases in the amount of hemoglobin can come about as a result of a decreased concentration of hemoglobin in the erythrocytes, or a decreased number of erythrocytes that contain a normal concentration of hemoglobin.

Decreased levels are found in anemia states, hyperthyroidism, severe hemorrhage and hemolytic reactions due to transfusions of incompatible blood, reaction to chemical, infectious and physical agents as well as various systemic diseases. Increased levels are found in hemoconcentration of the blood, chronic obstructive pulmonary disease and congestive heart failure.

tHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

tHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

Reference Interval

Total hemoglobin[1]

sample type	range, g/dL
whole blood	
female	11.5-16.1
male	12.0-17.4
new-born	13.4-19.8

3.2.8 Hemoglobin Oxygen Saturation (SO_2%)

When each heme group of the hemoglobin molecule is associated with one molecule of oxygen, the hemoglobin is referred to as oxyhemoglobin (O_2Hb). The amount of oxyhemoglobin, expressed as a fraction of the total functional hemoglobin (able to bind oxygen), is termed hemoglobin oxygen saturation (SO_2%). The largest portion (about 98%) of blood oxygen content is the oxygen bound to hemoglobin. The reference interval for arterial blood from healthy adults is typically 94 to 98%. Decrease in SO_2 below the critical level necessary for tissue oxygen saturation is a grave clinical situation. Low oxygen saturation may be caused by many of the same factors responsible for arterial *hypoxemia*. Low fractional oxyhemoglobin (FO_2Hb), defined as a fraction of total available hemoglobin, may also be caused by unusually large amounts of non-functional hemoglobins, high concentrations of deoxyhemoglobin, chemically altered hemoglobin or factors affecting the affinity of hemoglobin for oxygen, including: temperature, pH, PCO_2, 2,3-DPG concentration and type of hemoglobin.

Reference Interval

Oxygen Saturation[1]

sample type	range, %
whole blood, arterial	
new-born	40-90
thereafter	95-100

3.3 Limitations

The performance characteristics are affected by the following sample considerations:

The preferred test liquid is whole, human blood for all parameters. It is necessary to tonometer blood to obtain values to evaluate accuracy of PO_2 and PCO_2 because patient samples must be considered to be unknown. Tonometry of blood introduces potential errors unrelated to the blood gas system being evaluated. Accuracy of the gas values used, temperature control and thermostatting of the tonometer, humidification of the tonometry gases, duration of tonometry and transfer of the sample from the tonometer to the instrument for analysis are examples of potential pre-analytical error.

pH of blood cannot be predicted in tonometry. All tonometered samples analyzed in these studies were analyzed in duplicate on an Roche - AVL 995 to establish correlation. Precision of PCO_2 and PO_2 measurement, as well as pH was evaluated over a 20 day period using two OPTI R systems with two replicates per run using a commercially available solution of reduced bovine

hemoglobin which has been demonstrated to be comparable to tonometered whole blood[4]

The OPTI R system is designed to measure whole blood, serum or plasma to be controlled with aqueous solutions. Aqueous controls are portable and quite convenient to use with the OPTI R system, however, their low oxygen carrying capacity and temperature sensitivity is well known. Measurements of such materials are more prone to pre-analytic error as well as analyzer-specific errors, compared to similar measurements of whole blood. The OPTI R system is no exception to this, and demonstrates somewhat poorer PO_2 precision with aqueous controls than with whole blood, due to the large amount of plastic material comprising its disposable measurement chamber.

The OPTI R Analyzer's tHb measurement is sensitive to pathologically rapid sedimentation rates of the erythrocytes, often induced by excessive rate and amounts of rouleaux formation.[5] This is observable as rapid sedimentation and clarification due to erythrocyte aggregates falling to the bottom of the syringe within minutes of mixing. The OPTI R Analyzer breaks up most of the rouleaux and other aggregates by rapidly aspirating the whole blood sample with high shear rate, however in rare pathologic cases the rouleaux aggregates persist or reform during the aspiration and cause a positive tHb offset of up to 3 g/dL, typically within the range 7-12 g/dL.

Measuring Range:

pH	6.6 to 7.8	pH units
*P*CO2	10 to 200	mmHg
*P*O2	10 to 700	mmHg
Na^+	100 to 180	mmol/L
K^+	0.8 to 10	mmol/L
Ca^{++}	0.2 to 3.0	mmol/L
tHb	5 to 25	g/dL
SO_2	60 to 100	%

Any measurement outside the Displayable Ranges will be indicated on the display as ' LOW ' for values lower than the range and ' HIGH ' for values above the range. However, the printed report will show out-of-range values with reference to the end value of the measurement range; for example, the printed report will show a PCO_2 value of 220 mmHg as:

PCO_2 > 200 mmHg (Meas. Lim.)

[4] Mahoney JJ, Wong RJ, Van Kessel AL, Reduced Bovine Hemoglobin Solution Evaluated for Use as a Blood Gas Quality Control Material. Clin.Chem.39/5,874-79 (1993).

[5] J.B.Henry, Clinical Diagnosis and Management by Laboratory Methods, 19th Ed., 1996, p.590,777

3.4 Interferences

Optode pH measurements have a known sensitivity to the blood ionic strength[6], which is determined primarily by variation in serum levels of sodium. The OPTI R Analyzer utilizes an internal Na^+ sensor to actively compensate and correct for this sensitivity. That is, the OPTI R Analyzer's reported pH has no measurable interference from hyponatremic or hypernatremic samples, nor for ionic strength variations within the physiologic limits of 100 to190 mmol/L.

The OPTI K^+ sensor has no measurable interference from Na^+ variation within the range 100-180 mmol/L. The OPTI Na^+ sensor has no measurable interference from K^+ variation within the range 0.8-10 mmol/L.

The OPTI Na^+ sensor does exhibit a small interference from Li^+. Li^+ levels of 1, 2.5, 6.4 mmol/L will cause a positive Na^+ bias of 0.9, 1.2, and 1.3 mmol/L, respectively. A syringe sample anticoagulated with typical amounts of lithium heparin has 1-4 mmol/L of lithium, which offsets the measured Na^+ by less than 1%.

To minimize the interference from lithium, use syringes containing the lowest acceptable heparin level or a balanced heparin type syringe. Carefully follow the syringe manufacturer's recommendation regarding proper filling of the syringe. A partially filled syringe results in excessive lithium concentration.

Heparin salts are the only acceptable anticoagulant. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the electrolyte and pH sensors.

The OPTI Na^+ and K^+ results include an appropriate correction for pH at all values of pH. This correction may introduce an extra source of variability at the extreme values.

The OPTI Ca^{++} sensor does exhibit an interference from bisulfate and phenylacetic acid.

Selected substances endogenous and exogenous to human blood were tested for interference in accord with NCCLS EP7-P[7]. These substances were selected on the basis of their optical absorbance or fluorescence properties likely to affect the optical signal measured by the OPTI R Analyzer, or the optical properties of the sensor measured by the analyzer. To cause interference to the optical sensors, the substances must be highly mobile (low molecular weight) and highly colored, in order to penetrate the optode membrane barriers quickly (within the 90 sec. measurement interval), and then strongly absorb light or emit light of the proper color. To cause

[6] Wolfbeis OS, Offenbacher H, Fluorescence Sensor for Monitoring Ionic Strength and Physiological pH Values, Sensors and Actuators 9, p.85, 1986.

[7] NCCLS. Interference testing in clinical chemistry; Proposed Guideline. NCCLS Publication EP7-P. Villanova, PA; NCCLS, 1986.

interference to the tHb and SO_2 reflectance measurements, the substances must strongly absorb or scatter red or infrared light, relative to normal whole blood.

The following substances were tested in whole blood at the NCCLS-recommended test level or higher, and showed no interference to any measured analyte, including blood gas, electrolytes, and tHb/SO_2:

Bile Acids (30 µmol/dL)
Bilirubin (40 mg/dL)
Beta-Carotene (3.0 mg/dL)
Hemolysis (10%) During hemolysis K^+ is released from the blood cells thereby increasing the measured K^+. In the same manner, protein released from the cells binds ionized Ca^{++} and decreases the concentration. While an accurate value is reported, it will reflect the actual changes caused by hemolysis.
Lipemia (equivalent to 3000 mg/dL triglycerides)
Elevated white blood cell count (30,000 WBC/µL)

The following substances were tested in plasma at the NCCLS-recommended test level or higher, and showed no interference to blood gas and electrolyte analytes:

Coumadin (Warfarin) (12 mg/dL)
Dicumarol (Dicoumarin) (11 mg/dL)
Procain (Novacaine) (13 mg/dL)
Acetaminophen (Paracetamol) (20 mg/dL)

Fetal hemoglobin taken from cord blood extracts was tested and showed no interference to the tHb and SO_2 measurement.

The following interferents were quantified in whole blood, showing sensitivity to dyes similar to most CO-oximeters:

Substance	Amount	ctHb change (g/dL)	SO_2 change (%)
EXOGENOUS			
Cardio (Indocyanine) Green	0.5 mg/dL	+4.7	+4%
Evan's Blue	5.0 mg/dL	< 1	-17%
Methylene Blue	25 mg/dL	+3.0	-37%
ENDOGENOUS			
Carboxyhemoglobin	10%	-2.0	<2%
Carboxyhemoglobin	20%	–3.3	<2%
Methemoglobin	20%	+4.5	-7%

The following exogeneous interferents were quantified in tonometered plasma, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver.

(NOTE: all showed negligible interference to PCO_2 and PO_2):

Substance amount	pH change	Na^+ (mmol/L) change	K^+ (mmol/L) change	Ca++ change
Sodium fluorescein 25 mg/dL	unstable	unstable	-0.8	unstable
Cardio (indocyanine) green 0.5 mg/dL	+0.02	-15	-0.4	+0.01
Methylene blue 25 mg/dL	unstable	unstable	unstable	unstable

Rapidly sedimenting blood samples should be mixed thoroughly and immediately aspirated into the OPTI R cassette, as described above in "Handling and Storage of Samples", to ensure accurate tHb measurements. If allowed to sediment, the blood sample's reported tHb may be falsely high or low.

Only clear, uncolored quality control materials, such as Roche - OPTI-check brand aqueous controls should be used with the OPTI R system. Colored materials, including proficiency testing materials, may interfere with the pH or ion measurement, or fail to be properly aspirated.

The OPTI R system was evaluated for the interference of sample temperature on measurement (iced samples). No measurable sensitivity to sample temperature was found.

3.5 Sample Material

3.5.1 Sample Requirements

Blood sampling for analysis must be performed under proper medical supervision with details of collection, including sampling devices, site selection, sample handling documentation and specific procedures used approved by the personnel responsible.

3.5.2 Anticoagulants and Sample Collection Devices

Lithium heparin is the only acceptable anticoagulant for blood gas **and** electrolyte analysis. Lithium heparin, sodium heparin or balanced heparin salts are the only acceptable anticoagulants for blood gas analysis. Other anticoagulants such as EDTA, citrate, oxylate and fluoride have a significant effect on blood pH and electrolyte levels and should not be used. Lithium heparin should not be used for samples taken also for analysis of lithium.

3.5.2.1 Syringes

If liquid heparin is used as an anticoagulant, collection devices should be no larger than the amount of blood required to minimize the effects of dilution of the blood by the anticoagulant solution. Although plastic syringes are commonly used for collection of blood specimens for blood gas analysis,

there have been reports in literature regarding the use of plastic syringes when PO_2 values higher than normal are expected. Particular attention should be paid to cooling blood samples in ice water, because of the CO_2 and oxygen solubility in some plastics. If blood specimens are expected to have very high PO_2 values, care should be taken to analyze the specimen as quickly as possible following collection to avoid the need for cooling. *Attention should be paid to thorough mixing of whole blood samples prior to analysis, since sedimentation of blood cells affects the measurement of total hemoglobin.*

3.5.2.2 Capillary Tubes

Capillary blood specimens should be collected using capillary tubes which have a minimum volume, filled, of 125 µL. The Roche Capillary Tube, (Roche Reference Number 03113477180) is ideally suited with a volume, filled, of 200 µL. The Roche capillary tubes for pH, blood gas, and electrolyte analysis should not be used for samples taken for the analysis of lithium. Samples may be collected in capillary tubes after warming the area or otherwise stimulating it to promote arterial circulation before the puncture. The puncture should be made deeply enough to ensure a free and rapid flow of blood. Do not use clay-capped capillary tubes as the rough, broken edge left when the capillary is cut may cause damage to the OPTI R cassette fill port. Use only capillary tubes with fire-polished ends to prevent damage to the cassette. If a mixing flea is used, as required in some capillary tubes, take care to remove the flea prior to sample introduction to avoid damage to the cassette. Specimens collected in capillary tubes are stable at room temperature for up to 30 minutes after collection because of the rapid cooling of the sample accomplished during filling.

3.5.2.3 Roche Microsampler

Blood may be collected for analysis on the OPTI R with the Roche Microsampler to provide two filled capillary tubes.

After collection, the Microsampler should be capped and transported in a horizontal position to the instrument for analysis within 30 minutes, as with all specimens collected in capillary tubes.

3.5.3 Stability of Samples

Collect blood in a heparinized syringe, a capillary tube or an Roche Microsampler. Whole blood samples should be analyzed as soon as possible, ideally, within five (5) minutes after collecting the sample. For a brief storage of up to one (1) hour, the sample should be iced.

NOTE: Whole blood samples require the proper amount of anticoagulant to prevent the sample from clotting. DO NOT use anticoagulants such as EDTA, citrate, oxalate, etc. Use only heparin salts as anticoagulants.

NOTE: Sedimentation of red cells may occur rapidly in whole heparinized blood. This may effect your tHb results. Make sure your sample is free of trapped gas bubbles and completely mixed, by rolling the syringe between the palms of your hands and inverting end over end for at least one (1) minute, just prior to sample introduction.

NOTE: Always, follow proper safety procedures when handling biological samples.

3.6 Marketing of the Roche OPTI R Critical Care Analyzer

The **OPTI R Analyzer** and **cassette** will be available from **March 1, 2001** on and will fill an existing gap in the Roche critical care product portfolio. The OPTI R Analyzer is designed mainly for decentralized use in hospitals. The Operating Room (OR) will be the first choice customer because in the OR a rapid result and ease of use is mandatory to effectively manage the critical condition of these patients.

The OPTI R Analyzer will also be used in other Point-of-Care environments with low-to-medium sample throughput (ca. 3 – 12 / day) where portability e.g. battery operation is required. It will also fit into small laboratories where the offered parameter panel is sufficient and no-maintenance, easy operation and reasonable operating costs are important. Specifically the following departments within the hospital market may be targeted by the OPTI R Critical Care Analyzer:

- Operating Room
- Emergency Department
- Stat Laboratories
- Main Laboratories (backup for benchtop analyzers)

4 Medical Background

4.1 Blood Circulation

4.1.1 Types of Blood Vessels

4.1.1.1 Arteries

Arteries carry blood away from the heart muscle. Blood contained in the arteries is high in oxygen content and is bright red in color. The PO_2 and PCO_2 levels remain relatively unchanged until the blood reaches the capillaries. Arterial samples provide a good indication of the patients overall blood and body conditions. These type of samples also provide the clinician critical information regarding:

- Lung Function – Ability to exchange Oxygen and Carbon dioxide
- Cardiac (heart) Function – Assess blood circulation and fluid balance

4.1.1.2 Veins

Veins carry blood to the heart muscle. Blood contained in the veins is low in oxygen, high in carbon dioxide and dark red in color. Samples drawn from veins provides a good indication of local tissue function. However, these types of samples are not often used by clinicians because the results vary widely from site-to-site.

4.1.1.3 Capillaries

Blood contained in the capillaries is low in oxygen, high in carbon dioxide and dark red in color. Samples drawn from the capillaries offers minimal clinical information except for pre-mature babies (neonates). These type of draws are primarily performed in Neonatal Intensive Care Units.

4.2 What is an ABG?

An ABG or Arterial Blood Gas is a measurement of the patients pH, PCO_2 (partial pressure of carbon dioxide) and PO_2 (partial pressure of oxygen) in arterial blood.

4.2.1 Why does a Clinician Want an ABG?

Clinicians most often request an arterial blood gas since it is the…

- Best indicator of a patients oxygenation status (pH, PCO_2 and PO_2)
- Best indicator of a patients acid-base balance (BE and HCO_3-)
- It assists the clinician in identifying a cardiopulmonary crisis
- It assists the clinician in assessing the effectiveness of the patients therapy

4.3 Blood Gas Terminology

- Measured Values
  - pH Acid-Base Balance Information
  - PCO_2 Carbon Dioxide Partial Pressure
  - PO_2 Oxygen Partial Pressure
  - SO_2 Oxygen Saturation

- Calculated Values
  - HCO_3- Bicarbonate
  - BE Base Excess
  - BE_{ecf} Base Excess Extracellular Fluid
  - BEb Base Excess Blood
  - BE_{act} Base Excess at Actual O_2 Saturation

4.4 Normal Blood Gas Values

• pH	7.35-7.45	pH units
• PCO_2	35-45	mmHg
• PO_2	80-100	mmHG
• BE	0 +/- 2	mEq/L
• HCO_3-	24 +/- 2	mEq/L
• SO_2	90-100	%

4.5 Treatment of Abnormal Blood Gas Values

- Low PO_2
  - Need to provide more oxygen to the patient
  - Oxygen range can be Room Air (21% or 0.21) to 100%
  - Can be as simple as providing oxygen rich environment – patient breathes on their own
  - Can be as complex as forcing higher oxygen levels into the patients lungs

4.5.1 Types of Oxygen Therapy

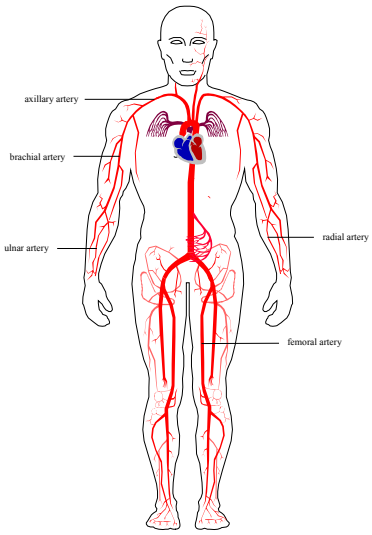
- Nasal Cannula
- Face Mask
- Ventilator
  - Provides Oxygen and Breathing Assistance
  - Controls rate and strength at which the patient breaths
  - Impacts carbon dioxide levels
    - Increased breathing rates = Lower carbon dioxide levels
    - Decreased breathing rates = Higher carbon dioxide levels

- General Terminology
  - PS Pressure Support
  - TV Tidal Volume
  - PIP Peak Inspiratory Pressure
  - Pplat Plateau Pressure
  - PEEP Positive End Expiratory Pressure

4.6 Arterial Blood Gas Sample

4.6.1 Arterial Blood Sample Sites

- Radial Arteries
  - Wrist Area
- Brachial Arteries
- Upper Arm Area
- Axillary Arteries
- Armpit Area
- Femoral Arteries
- Scalp Artery
- Neonatal ICU Patients



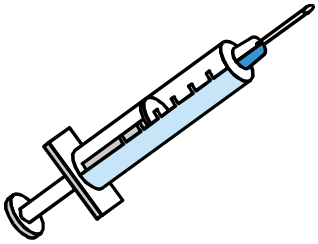
4.6.2 Arterial Blood Sample

- Exposure to room air alters PO_2 values
- PO_2 and PCO_2 values can change even while in a syringe
  - If placed in ice, the metabolic rate of the blood will decrease

4.7 Blood Gas Collection Devices

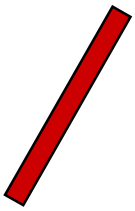
4.7.1 Syringes

- Blood Gas Kits
  - Heparinized Syringes
  - Brachial Arteries
    - Anticoagulant of choice – especially when electrolytes are being analyzed
  - Sodium Heparin
    - Less commonly used



4.7.2 Capillary Tube

- Capillary Tubes or Samplers
  - Heparinized
  - Glass
  - Sealant



4.7.2.1 Capillary Sampling

- Capillaries are close to the surface of the skin
- Good indicator of PO_2 delivery in babies
- Typical Heelstick Analysis

4.8 Blood Gas temperature Correction

- Direct relationship between Temperature and Pressure – impacts PO_2 and PCO_2 values
- Temperature impact on PO_2 is minimal
  - Example
    Patient Temperature changes from 37-39 °C, the impact on PO_2 is from 100 – 110 mmHg
- Temperature impact on PCO_2 is greater than PO_2
  - Example:
    For each degree Celsius elevation, the PCO_2 is impacted by 5%
- PCO_2 impacts pH
- Blood gas values are typically measured at 37 °C
- "Temperature Correction" is desired by clinicians

4.9 ABCs of Blood

4.9.1 Blood Components

- Red Blood Cells (RBCs) or Erythrocytes 45%
  - RBCs contain Hemoglobin (Hb)
    - Carries blood and Carbon Dioxide throughout the body
    - Each Hb molecule can carry up to four (4) oxygen molecules
    - Saturated Hemoglobin contains oxygen
    - De-Saturated (Un-Oxygenated or De-Oxygenated) Hemoglobin contains no oxygen
    - % Hb carrying O2 in Arterial Blood is known as Oxygen Saturation of Arterial Blood (SaO_2) or "Saturation"
    - Saturation reflects only a portion of available Hb
- Abnormal Hb Components
  - Carboxyhemoglobin – CO-Oximeter Measurement*
    - Hb combined with Carbon Monoxide, expressed as a percentage (%) of total hemoglobin. Provides clinical indication – Smokers (as high as 10%) Carbon Monoxide Poisining
- Fetal Hemoglobin (HbF) - CO-Oximeter Measurement*
  - Found in the fetus with greater affinity for O_2 than adult Hb. Approaches adult ranges around six (6) months of age
- Methemoglobin (metHb) - CO-Oximeter Measurement*
  - Dysfunctional Hb which cannot carry O_2. This can be acquired or attained from a congenital disorder

* CO-Oximeter – Most blood gas analyzers yield SO_2 readings that reflect a combination of saturated and unsaturated hemoglobin (Fractional and functional Hb). CO-Oximeters differentiate between saturated and unsaturated hemoglobin (Fractional and functional Hb). The OPTI R is NOT a CO-Oximeter.

- Plasma 55%
- White Blood Cells Less than 1%

4.10 Electrolytes

4.10.1 Electrolytes – What do they do?

The body requires Electrolytes for Metabolic activities. Electrolytes maintain water distribution in various body fluid compartments and are required for proper function of the heart and other muscles. These electrolytes regulate pH.

4.10.2 Sodium (Na^+)

- Maintains distribution of water and osmotic pressure in the extra-cellular compartment
  - High Na^+ identified by vomiting, diarrhea
    - Infusion of high salt IV solutions
  - Low Na^+ identified by vomiting, diarrhea, diuretics

4.10.3 Potassium (K^+)

- Potassium is a major intra-cellular cation. Disturbances in potassium levels have severe consequences on the human body leading to muscle weakness, paralysis, fast heart rate and cardiac arrest.
  - High K^+ identified by vomiting, diarrhea and dehydration. Severe burns will cause potassium levels to rise
    - Infusion of high salt IV solutions
  - Low K^+ identified by vomiting, diarrhea, cirrhosis
    - Diabetes – insulin therapy

4.10.4 Ionized Calcium (Ca^{++})

- Ionized Calcium
  - Ionized Calcium is the best indicator of calcium status in the human body.
  - Bone Mineralization
  - Neuromuscular excitability and contractility
  - Blood coagulation
- Total Calcium
  - 50% is Ionized (free or unbound calcium)
    - calcium binds to protein
- Normalized Calcium (nCa^{++})
- Calcium that has been "adjusted" to accommodate pre-analytical specimen issues (degradation of the sample)
- High Ca^{++} can lead to kidney failure and tumors
- Low Ca^{++} caused by major surgery, trauma or severe burns

5 Marketing Background

5.1 Premise

With the availability of the Roche OPTI R Critical Care Analyzer, Roche will be able to provide a complete portfolio of products to meet the needs of our Hospital Point of Care customers.

5.2 The Concept

The Roche strategy is to be the number one supplier of Hospital Point of Care solutions combining a broad portfolio of analyzers for blood gases, electrolytes, coagulation, troponin measurements and the connection IT solutions. These Hospital Point of Care tests help you to cope even more effectively with all the challenges waiting to confront you in Emergency, Intensive Care units and Operating Rooms.

Currently Roche offers the Roche OPTI Critical Care Analyzer (CCA) with single-use cassettes for POCT-users with low to medium sample throughput (up to 10 samples per day).

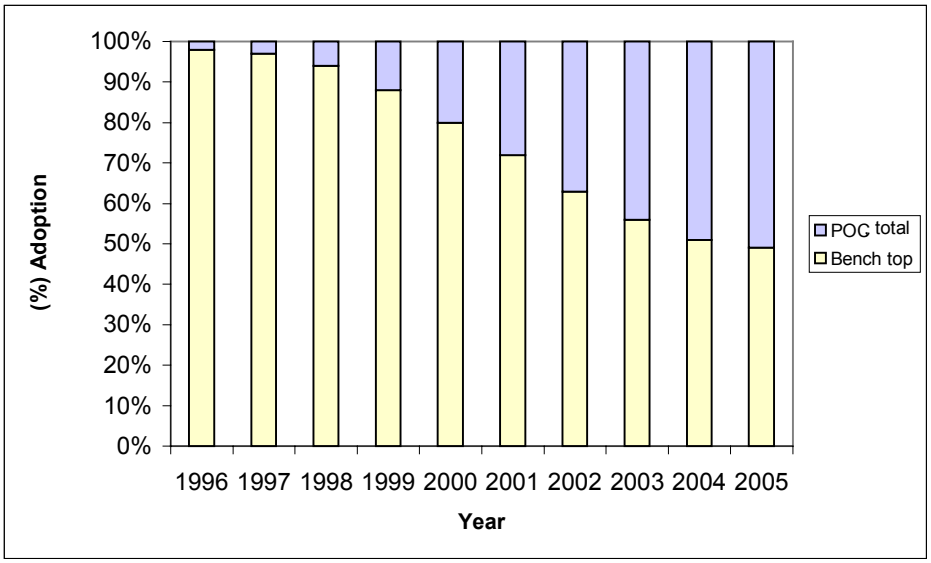
The Roche OMNI products are targeted for Hospital Point of Care -users with a high sample throughput of greater than 20 patient samples per day. Currently Roche does not offer any HosPoC – instruments for the "mid-range" sample throughput.

With OPTI R Roche is now able to fill the gap of the " mid range" sample throughput of 3-12 patient samples per day with a competitive parameter panel, "simple-maintenance" design and reasonable cost per sample.

5.3 Marketing the OPTI R Analyzer – Market Analysis

5.3.1 Market Potential

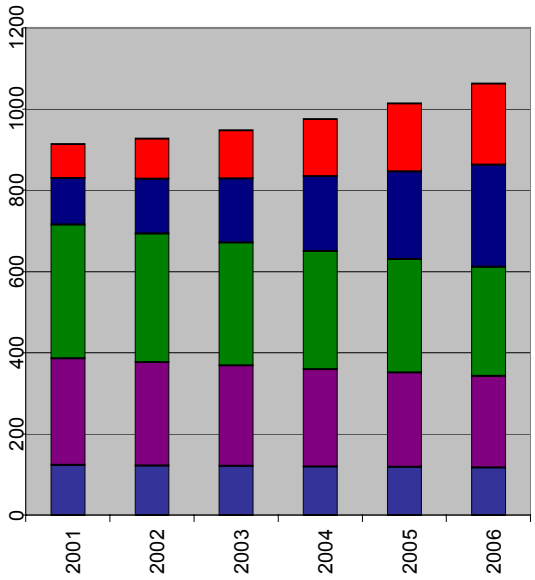
A study conducted by the Wilkerson group estimates that POCT will account for 51% of all critical care testing in 2005 (see graph 3 below).



Graph 3 - Market Development POCT, source: Wilkerson group 1996, 1998

The worldwide annual growth for the Hospital Point of Care systems is estimated as follows (see graph 4 below):

Systems	Annual CAGR
Single use/hendheld (OPTI CCA)	19 %
Small decentral benchtops (OPTI R / Omni...)	17 %
Big decentral benchtops	-4 %
Lab blood gas	-3 %
Electrolytes only	-1 %
Total	2,3 %



Graph 4 - Market development (Mio CHF), source: Business Plan Hospital Point of Care Blood Gas and Electrolyte Testing 2001

5.3.2 Point-of-Care Testing – US Hospital Survey

Many surveys and evaluations have been conducted in the context to POCT. A US hospital survey identified the most important advantages provided by POCT as seen by clinicians and lab personnel.

Advantages	%
Turnaround Time	91
Patient Satisfaction	34
Length of Stay	21
Visibility	17
Cost Reduction	15
Backup	14
Personnel Requirements	9

Bickford (1994) Clinics Lab Med 14:623

5.4 Why Point-of-Care testing?

Clinicians are less and less willing to accept turn-around-times (clinical TAT = time from order to treatment) of more than 5 min. for critical care analytes. STAT-labs have been created to reduce TAT, but on the other hand they have been labeled to be very expensive to maintain. This is mainly caused due to additional personnel and equipment cost. Clinicians feel that reduced TAT leads to more effective patient care and/or better patient outcome which in turn saves cost (total time from diagnosis, to treatment, to disposition). Lab people tend to not agree to clinicians perception of long TAT. Labs tend to define TAT as time between collection to reporting which in many cases is less than 5 min.

Nevertheless it is important that Laboratory Testing and Point of Care Testing are complementary.

The clinicians should define the needs and preferences and the laboratory should propose the dx infrastructure in which these can be served best because the “right solution”depend on several factors e.g. distances between ERs, ICUs, ORs and lab(s), test order “pattern” (menue; day/night; department....), methods for sample and information transfer.

Therefore the Hospital Point of Care Testing does not threaten the lab organizations.

On the contrary the POC Testing can be used to promote, defend and expand the hospital lab’s role.

What are the Critical Care Parameters?

Below is a list showing the 18 tests, which are important to the management of patients on a critical care basis. The analytes are listed in the order of importance listed by 54 participants of a focus panel consisting of nurses and physicians.

- Arterial blood gases
- Hemoglobin / Hct
- Electrolytes (Na^+ , K^+)
- PT
- PTT
- Glucose
- Calcium
- BUN
- Creatinine
- Complete blood count (CBC)
- Platelets
- Alcohol
- White blood count (WBC)
- Magnesium
- Activated clotting time (ACT)
- Cardiac Marker (Troponin I, T,)
- Creatine kinase (CK)
- Lactate

5.5 Consequence for the Roche Product Portfolio

There is a need for a fast, reliable, relatively low price blood gas / electrolyte analyzer that is easy to use and can be used on the spot without waiting for the result from the laboratory: The Roche OPTI R Analyzer

5.6 SWOT Analysis – Roche OPTI R Critical Care Analyzer

5.6.1 Strengths

- Innovative product features and reliable technology that provide accuracy, ease of use, minimum maintenance, and cost efficiency
- Small and portable instrument for decentralized use
- Rapid time to result – Approximately one (1) minute
- Easy handling does not require high skill or special training
- Flexibility with modular or cassette systems to accommodate both centralized or decentralized BG testing requirements
- Seamless integration of patient and quality control results directly into the facilities LIS/HIS with DataCare / OMNILink
- Roche broad Hospital Point –of Care portfolio
- Strong Roche market presence in the blood gas / electrolyte testing market

5.6.2 Weaknesses

- Lack of proof sources that support the BG analyzers and document the positive experience in prominent accounts
- OPTI R Menu limitation for the ER, ICU and CCU (missing creatinine, lactate and coag)
- Sample volume too large for neonatal samples (NICU)

5.6.3 Opportunities

- Use the power of the combination of the total Roche Hospital Point-of-Care product portfolio
- Gain access to key decision makers through Laboratory Systems and Diabetes Care account relationships in large hospitals, identify timing for replacement analyzers and potential for decentralized testing sites
  Leverage benefits of Data Management connectivity and data management for competitive replacements
  OPTI sales in the OR through targeting of profusionists with the value of measured hemoglobin versus conductive hematocrit (USA only)

5.6.4 Threats

- Price erosion caused by competitive pressures
- i-STAT next generation analyzer
- New Gem Premier PLUS Analyzer with color touch display (user interface)

5.7 OPTI R – Unique Selling Points (USPs)

- Room Temperature Storage of Cassettes at ALL times
  - No refrigeration of cassettes required – No time consuming equilibration
- Automatic Aspiration of Sample
  - Makes sampling **easy** and safe; Eliminates underfilling or overfilling the sensor cassette
- Barcode Calibration of Cassettes
  - No calibration codes for the operator to enter which eliminates potential for operator input error due to incorrect patient ID, calibration code and lot number information
- On Board Storage Capacity
  - > 150 patient records plus three (3) levels of quality control data for one (1) month stored on the analyzer
- Flexible Connectivity Options
  - Infrared (IR), RS-232, (both via ASCII, ASTM, or Mobil ASTM communication)
- Measured tHb and O_2 Saturation (SO_2)
  - Measured tHb is much more accurate than measured HCT through conductivity
  - I-STAT, Irma, GEM and ABL 70 all measure HCT through conductivity that can render a falsely decreased result when used in conjunction with plasma expanders (cardioplegia) in O.R. settings
  - Can lead to unnecessary transfusions
- Automatic Gas Calibration
  - Increases accuracy and stability
- OPTI R SnapPak™
  - Provides reagents for multiple tests and serves as a safe wash and waste reservoir

Ease of Use

- Always ready for patient analysis
- Uniform sample aspiration makes sample introduction operator independent
- Sample aspiration reduces training requirements, only few hours needed
- Direct sampling from standard syringes, capillaries and Roche Microsampler
- Convenient cassette storage at room temperature (6 months from date of manufacture at 4-30 °C, 39-86 °F)
- Maintenance free optical system
- Light weight and easy to transport with built-in handle
- Power supplied by either A/C or rechargeable battery

- Multi-lingual software (English/German/French/Spanish/Italian/Japanese) and user interface
- Flexible set up functions to accommodate user preferences
- Password protected system configuration menus
- Wireless data download via infrared data port

Accuracy and Precision

- Results comparable to reference benchtop analyzers
- All sensor cassettes have a six point factory calibration for all analytes
- Full 1-point gas calibration for PO2 and PCO2 after each sample measurement or minimally at 30 minute intervals
- Uniform sample aspiration assures consistent results, avoiding sampling technique dependent errors
- On-board quality control program stores 1 month of QC results at three (3) levels and statistical report
- User programmable reference ranges with auto alerts
- Self diagnostic program
- Storage for > 150 patient results
- Fully automatic, tracking barometer for accurate blood gas results
- Clear, easy to read thermal printout from on-board printer

Economy

- Convenient cassette storage at room temperature (6 months from date of manufacture at 4-30 °C, 39-86 °F)
- Cost saving opportunities due to improved turn-around-time and faster clinical decisions (results available in approximately 1 minute after sample aspiration)
- Accurate and precise analysis obtained by non-technical personnel
- Reduced training requirements due to high degree of automation
- Minimum maintenance requirements

Convenience/Flexibility

- Easy to use for syringe, capillary, or Roche Microsampler
- Small size offers the opportunity of location near to the patient, no special accessories are required
- Convenient cassette storage at room temperature (6 months from date of manufacture at 4-30 °C, 39-86 °F)
- Analyzer status reports on clear easy to read printout
- Calibration data scanned in utilizing the built-in barcode reader
- Easy to clean maintenance free optical system
- No special collection devices required, standard procedure and material accepted
- Reports a full menu of calculated parameters
- Correction for patient temperature
- Input values for patient and operator IDs, as well as accession numbers can be printed on the patient report
- Input for various ventilator settings
- Input fields for Sample Type, Ventilator Mode and O2 Modes
- Automatic short sample and bubble detection

- Automatic detection and early warning for low reagent and gas as well as battery condition

Safety

- Biohazard waste is contained in the OPTI R SnapPak for safe disposal
- Maintenance free measurement system
- Automatic bubble and short sample detection
- Cassette and OPTI R SnapPak – in place detection

5.8 Positioning

Roche offers are broad basket of blood gas and electrolyte analyzers, ideal for Hospital Point of Care Testing.

The "Top-of-the-line" **benchtop system** (Roche OMNI) which supersedes comparable competitive instruments with regard to user interface, data management and sensor technology. Its parameter panel and its features make the OMNI not only ideal for the laboratory but also for "Near Patient Testing" sites with high sample volume requirements. The modular design however makes the OMNI quite complex which negatively influences its reliability and leads to relatively high maintenance requirements thus compromises its application for POC testing.

The **Roche OPTI R** analyzer is ideally suited for use in Hospital Point of Care testing sites, as well as a backup instrument in laboratories, where sample volumes range from **three to twelve samples per day**. Its design provides operation by minimally trained personnel and requires little maintenance.

Roche also offers the OPTI CCA Critical Care Analyzer, a portable instrument, which is ideal for Near-Patient-Testing in **very low volume** (**1 - 3 test per days**) accounts due to the **single use cassettes**.

5.9 Target Customers

The **OPTI R** systems will be used in every Hospital Point of Care testing site with low-to-medium sample throughput (**ca. 3 – 12 / day**) where portability e.g. battery operation is required. It will also fit into small laboratories where the offered parameter panel is sufficient and no-maintenance, easy operation and reasonable running costs are important.

Specifically the following departments within the hospital market will be targeted by the OPTI R:

- Operating Room
- Emergency Department
- Intensive Care Unit
- Stat Labs
- Main Laboratory

5.10 Effective Selling Messages

5.10.1 Operating Rooms / O.R. Suites

Typical Audience/Operators

- Perfusionists (US Market)
- Cardiac Surgeons
- Anesthesiologists

Clinical Interest

Typical application of critical care analysis is the ***monitoring*** of a patient during surgeries with major blood loss i.e. open heart, organ transplants etc. Main goal is to maintain tissue (brain) oxygenation, cardiac and renal function during operation. Another goal is to prevent excessive blood transfusions (cost) by cooling the body down, keep PO_2 very high and if necessary operate with lowest possible tHb (6-8g/dl).

Main Parameters Needed

*P*O2, tHb/SO_2 - to determine tissue oxygenation, oxygen transport function
tHb - indicator for blood transfusion
pH, *P*CO2, - to determine the acid/base balance e.g. respiration
Na^+ , K^+ - kidney (renal) function, (nerve and muscle function)
Calcium - in open heart: Ca^{++} is the main controlling ion for contraction of the myocardium (heart muscle), it also plays a role in blood coagulation

Critical issues for the user

Sampling - ease-of-use (aspiration vs. injection), Turn-Around-Time, analysis time, tHb measurement, Ca^{++} analysis, cassette logistics, instrument and analysis reliability, maintenance, size, battery operation.

Less Critical

Sample volume, Data management

Typical sample throughput

1-30 per day depending on type of operating room (OR) and type of surgeries (cardiac has more than general surgery).

Important OPTI R features to highlight

- Uniform sample aspiration reduces user training requirements
- tHb measurement / SO_2 measurement
- Ease of use – Low complexity
- Battery / mains operation
- Convenient cassette storage at room temperature (RT) for 6 months
- Minimum maintenance requirements

Additional information

Anesthesiologists are technically oriented people, they do not shy away from analyzer operation. If Analyzer is used in the individual OR - the Anesthesiologist looks for analyzers, which do not need attention (they want to keep their eyes on the control board). If used outside the operation room it is most likely operated by an OR nurse. Here ease-of-operation, low maintenance is key.

Decision Drivers

- Speed to result
- Ease of Use-Including QC
- Menu
- yData Connectivity

Additional OPTI R Features to Highlight

- Ease of Sampling
- Barcode Reader
  - Ability to enter patient data
- Fast Analysis Time
  - Approximately 1 minute from sample introduction
- Last Patient Recall
  - Eliminates the need for entering patient id and demographic information more than one time during the case
- Wide Ambient Temperature Range
  - Easily accommodates all OR temperature needs
- tHb and 02 Saturation Measurement
  - Directly measured tHb might reduce unnecessary transfusions as opposed to HCT measured through conductivity (plasma expanders on HCT)
- Data Storage on the OPTI R
  - Lab will be assured that all regulatory requirements are being met ; Perfusionists and other O.R. staff aren't concerned with CLIA however this will help appease what ever group holds the license
- Transportability to Central Area for Data Download or QC
  - Convenient to take to a central repository area where they can be easily dropped off and picked up ready to go the next day

5.10.2 Intensive Care Unit / Coronary Care Unit

Typical Audience/Operators

- Nurse Manager
- Respiratory Care Practitioners
- ICU Physicians
- Medical Director

Clinical Interest

Typical application of critical care analysis is the ***monitoring*** of a patient in critical condition or recovery after an event i.e. after surgery or trauma like burn. Main goal is to stabilize and ultimately to facilitate an improvement of the patients respiration, cardiac and renal function i.e. get him/her off a ventilator and/or infusions.

Main Parameters Needed

*P*O2, tHb/SO_2 - to determine tissue oxygenation, oxygen transport function
tHb - indicator for blood loss, internal bleeding after surgery
pH, *P*CO2, - to determine the acid/base balance e.g. respiration
Na^+ , K^+ - water balance, kidney (renal) function, (nerve and muscle function)
Glucose - monitoring of diabetes patients as well as in patients with liver or pancreas problems

Critical issues for the user

Turn-around-time, ease-of-use (reduced training requirement), accuracy and precision of results to base decisions on, calculated parameters (RT), low maintenance of the equipment (clot removal), QC issues (perceived as additional paperwork), portability (size), logistics (cassette availability), cost considerations compared to bench top analyzers as alternative

Less Critical

Sample volume

Typical sample throughput

10-100 per day depending on number of ICU beds

Important OPTI R features to highlight

- Uniform sample aspiration reduces user training requirements,
- Aspiration from most types syringes,
- Convenient cassette storage at Room Temperature for up to 6 months from date of manufacture
- Minimum maintenance requirements,
- Data management system (integration)

Additional information

Nurses like easy and fast access to the results required by the physician (TAT) to start there action asap. They don't like to be involved in technical issues (maintenance, QC, clot removal etc.). ICUs are not the primary target market for GEM Premier and Radiometer ABL70, because both analyzers are not easy to transport, they offer no battery (GEM Premier) or no adequate battery operation (Radiometer ABL70).

Decision Drivers

- Ease of Use
- Logistics/Storage
- Data Transmission into HIS/LIS
- Quick Turn-Around-Time

Additional OPTI R Features to Highlight:

- Ease of Sampling
  - Automatic aspiration of sample eliminates special techniques and back splatter potential from injection; **Minimizes training requirements**
- Automatic Calibration and Barcode Capability
  - No need to manually enter cal data or patient data
- Room Temperature Storage
  - Eliminates having to manually record "new" out of refrigerator expiration date; Waiting for cassettes to equilibrate, etc. (*Won't be a big issue unless they have been exposed to I-Stat*)
- Data Storage and Flexible Connectivity
  - Ensures regulatory compliance with easy transmission of data; Infrared will be big issues because they are used to hard wiring

5.10.3 Cardiac Catheterization Lab

Angioplasty – Opening obstructed arteries, Stents used to "prop" arteries open

Cardiac Catheterization – Diagnostic test-dye is injected into coronary artery with Xrays

Typical Audience/Operators

- Medical Director
- Nurse Manager

Clinical Interest

No Additional Information Acquired

Main Parameters Needed

No Additional Information Acquired

Critical issues for the user

No Additional Information Acquired

Less Critical

No Additional Information Acquired

Typical sample throughput

No Additional Information Acquired

Important OPTI R features to highlight

- Quick Turn-Around-Time
- Measured vs. Calculated tHb and O2 Saturation
- Portability
- Sample aspiration (training, analytical reliability)
- Convenient cassette storage at Room Temperature for up to 6 months from date of manufacture
- Minimum maintenance requirements

Additional information

No Additional Information Acquired

Decision Drivers

- Quick results, Ease of Use
- Measured (versus calculated) O2 saturation results
- Accuracy

Additional OPTI R Features to Highlight

- Quick TAT (Turn Around Time)
  - Physicians want immediate results during cath procedures in order to benchmark their progress
- Measured versus Calculated tHb and O2 saturation Results
  - provides physicians with extremely accurate results for their procedures
- Portability of the OPTI R
  - Makes it easy for the nursing staff in transporting the instrument from room to room in the cath lab
- Auto Aspiration Features
  - Staff in this area is very busy-hih level of interest in time saving features
- Ability to Standardize to One (1) Instrument for both Blood Gas and Co-ox (tHb and O2 saturation) needs
  - Standardization to one (1) vendor results in overall cost savings

5.10.4 Small Laboratories

Typical Audience/Operators

- Laboratory Director
- POC Coordinator (if applicable)
- Chemistry Supervisor

Clinical Interest

The laboratory serves the units mentioned before. Their main purpose is to provide the critical care sites with accurate and precise results, based on the analytes/parameters ordered. The lab knows the different analytical methods and their limitations from a analytical perspective. In most cases the lab is responsible for quality of results and therefore for QC. In most cases the lab holds the license to do critical care testing. Therefore most of the POCT is done under the license and responsibility of the lab. The lab plays in many cases a supervisor role for POCT. The POC-coordinator is mostly a lab person.

Main Parameters Needed

The laboratory has the potential to provide all parameters asked for in a hospital not only critical care parameters.

Critical issues for the user

Analytical performance (accuracy and precision and correlation to lab system), daily QC, user training, cost per test, sample throughput, reliability and robustness of the system as well as data integration with the LIS/HIS system are the main concerns of the lab

Less Critical

Ease-of-use, size, weight, portability, battery operation

Typical sample throughput

20 - 250 per day

Important OPTI R features to highlight

- Analytical performance (correlation)
- 6-pt. factory calibration / 1-pt. on-board buffer/gas calibration
- Sample aspiration (training, analytical reliability)
- Data transmission (IR)
- Convenient cassette storage at Room Temperature for up to 6 months from date of manufacture
- QC lock-outs
- Minimum maintenance requirements

Additional information

Labs wants to maintain control for different reasons – Point out the OPTI R features which help to maintain control such as:

- Password protection (PW1, PW2, PW1+PW2) – two levels limit access to various system functions (authorized user, administrator levels or both)
- QC Lockouts – provide security to help hospitals maintain their QC policies

- Secure Operator ID's limits analyzer access to properly trained, authorized users.

Decision Drivers

- Regulatory concerns – Remaining compliant
- Connectivity – Maintaining control
- Performance – Correlation to traditional laboratory instruments
- Menu

Additional OPTI R Features to Highlight

- Connectivity Options
  - Makes downloading patient and QC samples simple so they remain in control no matter who performs the test
- QC Lockout
  - Ensures that testing is not done on an analyzer that has not passed QC, even when they cannot physically be there
- Data Storage and Flexible Connectivity Automatic Aspiration of Sample
  - Demonstrates overall ease of use and low training requirements (especially important to POC coordinators who are responsible for training activities)

5.10.5 Emergency Room

Typical Audience/Operators

- Nursing Staff
- Physicians

Clinical Interest

Analysis of critical care parameters are needed to find a diagnosis. Emergency patients can be categorized into three groups: the ones who do well and need no test, the ones who are obviously sick and need ABG, tHb and Glucose. And last the ones who are not clearly in either group needing a lot of different tests for diagnosis.

Analysis of critical analytes are indicated if patients are unconscious or appear to have respiratory problems (heavy breathing, obstruction or trauma of airways, pale or blue skin) and/or with cardiac problems (chest pain, arrythmia, low pulse etc.).

Main Parameters Needed

*P*O2, tHb/SO_2 - to determine tissue oxygenation, oxygen transport function
tHb - indicator for blood loss (blood transfusions)
pH, *P*CO2, - to determine the acid/base balance
Na^+, K^+ - water balance, kidney function, (nerve and muscle function)
Glucose - Test for diabetes

Critical issues for the user

Turn-around-time for making a critical decision, ease-of-use (training requirement), system robustness, accuracy and precision of results, low maintenance incl. blood clotting, QC issues (no time for QC), portability

Less Critical

Sample volume, cost

Typical sample throughput

Varies, between 3-15 per day, depending on size of department

Important OPTI R features to highlight

- Ease-of-use i.e. automatic sample aspiration (no user interaction), failure safe sample measurement
- Simple user interface
- Low maintenance requirement
- Cassette storage (esp. since volume varies so much)
- Battery and mains operation (portability)
- Easy data integration (no user interaction)

Additional information

No Additional Information Acquired

Decision Drivers

- Ease of Use – Low complexity
- Minimal Maintenance requirements
- Reliability
- Connectivity

Additional OPTI R Features to Highlight

- Connectivity Options
  - Makes downloading patient and QC samples simple so they remain in control no matter who performs the test
- Data Storage and Flexible Connectivity Automatic Aspiration of Sample
  - Demonstrates overall ease of use and low training requirements (especially important to POC coordinators who are responsible for training activities)
- Ease of Sampling
  - Automatic aspiration of sample eliminates special techniques and back splatter potential from injection; **Minimizes training requirements**

5.10.6 Information Service (IS) Department

Typical Audience/Operators

- IT specialist
- Network Specialists
- System Manager

Interest

Again, the IT or IS department is a service unit for the hospital. They have to ensure that data and information travels seamless through the hospital system and is made available where needed and in the format needed. They have to integrate many diversified systems into one (LIS, HIS, analyzers, administration, imaging etc.) - called interfacing.

Critical issues for the user

Interfacing is a very complex topic. Therefore, the IT department asks for analyzer/ data management systems which interface with their system without adding excessive cost and/or complexity i.e. special wiring, special hardware, software changes. There are standard interface formats and protocols which make interfacing easier and more cost effective. Ideal situation: The standard network system together with their LIS/HIS system can be used.

In the near future we will provide the solution for all these IT demands by offering you our DataCare POC Information Management & Connectivity software. The software provides bi-directional data communications with Roche blood gas, glucose and coag devices, remote connectivity, LIS/HIS interfacing and regulatory compliance. The intended users are Point of Care Coordinators & Respiratory Manager`s managing POC & Critical Care Testing inside and outside of the central laboratory to maintain quality oversight and regulatory compliance.

Important OPTI R features to highlight

- ASTM and ASCII data protocol
- Standard serial port (RS232)
- Serial IR port
- Data integration using DataCare / OMNILink
- ASTM / HL 7 interface of DataCare / OMNILink to HIS/LIS
- Data integration of not only POCT but also bench-top

Additional information

The OPTI R can be directly interfaced to the facilities HIS/LIS system. However, this requires the facilities IT person to generate a parse (translator) program to act as an interface between the OPTI R and the facilities system.

Decision Drivers

- Connectivity – Data interface to the facilities system

Additional OPTI R Features to Highlight

- Connectivity
  - Identify the connectivity options – RS-232 (hardwire), Infrared (wireless), ASCII, ASTM or Mobil ASTM all set at 9600 baud

5.10.7 Hospital Administrators

In any hospital the administrators are getting more and more important in the decision making process when new investments are at stake. Only a cost-benefit analysis will convince them to invest into new instruments. The time to send the samples to the central lab, run the sample and communicate the result, may take up to several hours.

5.10.8 Private Hospital Sites

When looking at our potential customers, the private hospital sector is very promising especially among developing nations. In many countries the private sector is less price-sensitive, has higher budgets and are generally more interested in the latest technological developments in order to offer their patients/customers the best, fastest and most reliable service possible. In many countries the 'Early adopters' for our OPTI R Analyzer will come from this group with its entrepreneurial touch.

5.10.9 General Practitioner (GP)

The General Practitioner is not the main target customer for the OPTI R Analyzer. Nevertheless there is a GP-market: In the GP-scenario with the OPTI R Analyzer physicians generally do not have rapid access to lab results. This can cause unnecessary delays as well as unnecessary hospitalization. In some cases, the OPTI R Analyzer can facilitate decision-making.

5.11 Sales Strategy

In countries where blood gas analyzers are already implemented it is important that all potential OPTI R analyzer customers are contacted to be taught about the availability of the new Roche OPTI R Analyzer and to be offered more information. On the benefits of Point of Care technology and the features and benefits of the OPTI R Analyzer which differentiate this technology from our competitors.

Use the 3 key success factors:

- Roche´s high familiarity rates at all target groups
- High attractiveness for potential customers
- High customer`s loyalty

The sales strategy will depend on the country that is involved but….

In many countries the main customer "Operating Room" is not yet visited by the Roche sales force. The launch/availability of the new Roche OPTI R Analyzer with reusable cassettes gives us the opportunity to contact this customers, talk about Hospital Point of Care Testing, our broad product portfolio and service concepts and the resulting benefits for the customers. We must have a new focus on this customer group if we want to sell the Roche OPTI R Analyzer successfully.

In addition we also have to look after our customers in the decentralized wards (ER, ICU and CCU).

Nurses should also be taken into account when promoting the OPTI R Analyzer, as they, in most cases, will be the ones doing the measurements. Demonstrating to them the easy handling, should make them confident with our product.

5.12 The Sales Process

Common Customer Questions / Our Answers

How does the OPTI R measure tHb and SO2?

The OPTI R utilizes a technology known as optical reflectance using a single laser diode located in the cover of the sample measurement chamber. Three different wavelengths are utilized in these measurements, including two for tHb and one for SO2. The wavelengths used were selected to minimize interference from one another.

Can the OPTI technology identify patients who smoke or are suffering from smoke inhalation?

No, the OPTI R's tHb value includes measurement of Oxy-hemoglobin and Deoxy-hemoglobin levels. When assessing for smoke inhalation, physicians are interested in Carboxyhemoglobin measurements which the OPTI R does not measure.

What type of sample can be measured on the OPTIR Analyzer?

- Whole Blood
- Serum
- Plasma
- Non-colored (containing dye) aqueous quality control materials

How does the OPTI R handle hemolyzed blood?

The OPTI sensors are not affected. This also applies for the tHb and SO_2 analysis.

Can the OPTI R handle iced samples?

Yes, all samples are heated to 37 °C by the OPTI R's solid state heater. The entire measuring chamber is carefully thermostated. Blood analysis is does not begin until the temperature has been reached and is stable.

The OPTI R Analyzer has automatic sample aspiration, How does the competition compare with this?

The OPTI R is the only point of care instrument that contains an automatic sample aspiration feature. Other point of care competitive systems require an "injection" or "positive pressure" method of sample insertion, resulting in a potential for blood spillage, and contributing to an overall technique dependent testing process.

Can I run two different quality control materials interchangeably on the OPTI R?

Yes, but the OPTI will not store the results in its QC database and will therefore neither calculate nor print any QC statistics.

Can I run OPTI-check as a patient sample?

Yes, however the results will not be stored in the QC database and the results for tHb and SO2 will be suppressed since the analyzer knows it is not running a whole blood sample.

What is the analysis methodology used by the OPTI R Analyzer?

- Optical Fluorescence for the direct measurement of pH, PCO2, Po2, Na+, K+ and Ca++
- Optical Reflectance for the direct measurement of tHb and SO2

Is this a new methodology?

The methodology is based on the experienced, reliable and well excepted optical sensor technology.

Why isn't a reference electrode utilized in the OPTI R Analyzer?

In the fluorescence method, the OPTI R measurement changes light intensity. The Roche OPTI R cassette contains a small amount of a known concentration of buffer. Light with a known intensity is projected onto the optode. Based on the concentration of the buffer, the optode fluorescence emits a light of a different intensity. This intensity is then compared to the original calibration. An unknown sample can then be aspirated into the cassette. The intensity of light emitted by the sample is compared to the calibration curve and the analyte concentration is calculated.

Why is a humidifier no longer used?

The OPTI R cassette contains a liquid buffer that is used for calibration verification. The evaporated water from this buffer saturates the whole sample path with water vapor. This vapor is used to humidify the calibration gas. After a patient or QC sample has been measured the cassette is washed using buffer solution contained in the OPTI R SnapPak and the process starts all over again.

When was the first OPTI Analyzer introduced?

- The OPTI 1 Analyzer, which measured pH, PCO2 and PO2 using the same measurement technology as the OPTI R was introduced in 1995.
- The OPTI Critical Care Analyzer (CCA), which measure(s) pH, PCO2, PO2, tHb, SO2, Na+, K+, Ca++ and Cl- was introduced in 1998.

What is the difference between disabling and blanking a parameter?

Disabling – This feature is configured under Setup. It allows the administrator to remove parameters (tHb/SO2 or Ca++ only) from the display, printout and export. It also removes any calculated parameters which utilize this measured parameter. Disabled parameters are not QC controlled.

Blanking – This feature is configured under Setup. It allows the user to remove any parameter from the printout and export during the measurement run time "Edit Patient Data". Blanked parameters are still displayed and are under QC control.

What is the purpose of the 4-digit PIN#?

The 4-digit PIN# offers true security, if enabled under Setup, the user will be prompted for his/her PIN#, however the user ID number is what will be printed on the patient report. this prevents anyone from utilizing a number on the printout to gain unauthorized access to the analyzer.

What Proficiency Testing Material is qualified for use on the OPTI R Critical Care Analyzer?

At the present time only the CAP "AQ" survey material is qualified for use on the OPTI R Analyzer. This survey material supplies values for all parameters measured on the OPTI R except tHb and SO2 and should be reported using the OPTI R code supplied with the material.

How do I report tHb and SO2 for proficiency testing?

According to CAP, if no compatible material exists, then the facility must run split samples (1-2 per month) between a predicate device and the OPTI R to establish proficiency on the OPTI R. The differences between these measurements are established and documented as acceptable by the laboratory director. If the measurements exceed this difference, the laboratory director must then document the corrective action taken. The key

to success with this issue is DOCUMENT – DOCUMENT – DOCUMENT….

Can I interface the OPTI R Analyzer to a computer based data management system?

Yes, The OPTI R has two (2) serial interfaces including a standard 9-pin RS-232 port and an infrared port which will allow interfacing to a computer using either ASCII or ASTM data transmission.

Can I interface the OPTI R directly to a hospital system?

Yes, however this requires the facilities IT person to generate a "PARSE" program to act as an interface (translator0 between the OPTI R and the facilities system.

5.13 Pricing

As the **Roche OPTI R** system should be positioned between OPTI CCA ($\leq$ 3 tests/day) and OMNI C (> 10 tests/day) therefore our recommendation is to offer the OPTI R cassette box (4cassettes per box) for an AUP of 185 USD to 235 USD.

5.14 Advertising / Promotion / Printed Materials

5.14.1 Promotion

Available for launch

Product Brochure – OPTI CCA / OPTI R "Multiple Solutions for Multiple Situations"
AVL Part Number CH3724/ Roche Part Number 3141896
Product Flier - Technical Specifications, OPTI R "The Time-saving Solution for Multiple Situations"
AVL Part Number CH3723

5.14.2 Intranet

The related Intranet pages will be updated to include detailed information e.g. abstracts on all OPTI products, including the OPTI CCA and OPTI R.

6 Technical Features

6.1 OPTI R Critical Care Analyzer – The Analyzer in brief

The OPTI R Critical Care Analyzer is intended to be used for the measurement of pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb and SO_2 in samples of whole blood; and pH, Na^+, K^+ and Ca^{++} in serum and plasma, in either a traditional blood gas, Point-of-Care locations or clinical laboratory setting by personnel minimally qualified to perform and report these results.

6.2 Brand Names

OPTI R is the current brand name of the analyzer. With regard to the Roche Design Guidelines.the brand name will be changed to **Roche OPTI R** in Quarter II 2001 earliest. Therefore I hope you understand that we use the new brand name in advance here.

6.3 Order Check List

Global Material No.	Mannheim Material No.	AVL No.	Material Description	Remark	Quantity	*Order Guide*	German	Engl Intl	Engl US	Spanish	Italian	French	Japanese
03157377001	3157377001	GD7044	Analyzer, OPTI R				X	X	X	X	X	X	X
			including (not to be mentioned in order)										
			BP7091 - Analyzer, OPTI R										
			including (not to be mentioned in order)										
			BP7554 - SRC - Level 2										
			BP7542 - Cassette - tHb Calibration										
			BP7113 - KIT, ACC, OPTI R, GENERIC including										
			BP7007 - ASSY, BATTERY, COMPLETED										
			BP7110 - PACK, SHUTDOWN, OPTI R										
			BP7111 - CASSETTE, SHUTDOWN, OPTI R										
			EI7004 - SUPPLY, PWR, LOW VOLTAGE, OP										
			HP0070 - PAPER, TH. PRINTER, ROLL, OPT										
			MC0007 - SYRINGE, 12 ML WITH TAPERED T										
			MK0056 - BOTL 100 ML NAT. PLAS										
			RE7053 - CLOSURE STRIP, FLUID PACK, O										
			YA5020 - STYLET, PROBE, 9110										
			AT7042 - INSERT, Y2K CERTIFICATE, OPT										
			BT7006 - LITERATURE PACKAGE, MSDS, OP										
			EX0173 - CABLE, PWR, EUROPEAN										
			EX0197 - CABLE, POWER, 498/13 2M										

Additional items which must be ordered in selected version													
03107671001	3107671001	PD7033	MANUAL, OPERATOR´S, GERMAN	GERMAN			X						
03107680001	3107680001	PD7034	MANUAL, OPS, INTERNATIONAL	ENGL INTL				X					
03107698080	3107698080	PD7035	MANUAL, OPERATOR´S, FRENCH, O	FRENCH		NOT RELEASED						X	
03107701036	3107701036	PD7036	MANUAL, OPERATOR´S, SPANISH	SPANISH		NOT RELEASED				X			
03107728050	3107728050	PD7037	MANUAL, OPERATOR´S, ITALIAN	ITALIAN		NOT RELEASED					X		
03140873001	3140873001	AT7036	INSRT, QUICK REF GUIDE, ENGL	ENGLISH				X	X				
03140881001	3140881001	AT7037	INSRT, QUICK REF GUIDE, GERMAN	GERMAN			X						
03140890001	3140890001	AT7038	INSRT, QUICK REF GUIDE, FRENCH	FRENCH		NOT RELEASED						X	
03140903001	3140903001	AT7039	INSRT, QUICK REF GUIDE, SPANISH	SPANISH		NOT RELEASED				X			
03140911001	3140911001	AT7040	INSRT, QUICK REF GUIDE, ITALIAN	ITALIAN		NOT RELEASED					X		
03143503001	3143503001	BP7112	US, ACCESSORY KIT, OPTI R	ENGL (US)					X				
			PD7032 MANUAL, OPERATOR´S, ENGLISH										
			BT7005 Literature Pkg, OPTI R, US										
			PV7003 Video, Instructional, OPTI R										
Additional items which must be ordered													
Optional items													

Global Material No.	Mannheim Material No.	AVL No.	Material Description	Remark	Quantity	Order Guide	German	Engl Intl	Engl US	Spanish	Italian	French	Japanese
Items which have to be available for installation													
CONSUMABLES NEED FOR INSTALLATION													
03133532180	3133532180	BP7601	CASSETTE, E-CA 25 TYPE (4 per box)	Cassette			X	X	X	X	X	X	X
03133559180	3133559180	BP7600	Syring Adapters (125 per box)	Adapter			X	X	X	X	X	X	X
03144267001	3144267001	BP7592	ringe Adapters (30 per box)	Adapter									
Solutions													
03113027180	3113027180	HC7008	SOL, OPTI- CHECK, TRI- LEVEL	Solution			X	X	X	X	X	X	X
03172996180	3172996180	BP7092	OPTI R SNAPPACK	Solution			X	X	X	X	X	X	X
Gas utilities													
03112373180	3112373180	BP7001	ASSY, GAS, BOTL, OPTI 1	HarzardousMatl			X	X	X	X	X	X	X
CONSUMABLES													
03133532180	3133532180	BP7601	CASSETTE, E-CA 25 TYPE (4 per box)	Cassette									
03133559180	3133559180	BP7600	Syring Adapters (125 per box)	Adapter									
03144267001	3144267001	BP7592	ringe Adapters (30 per box)	Adapter									

Global Material No.	Mannheim Material No.	AVL No.	Material Description	Remark	Quantity	*Order Guide*	German	Engl Intl	Engl US	Spanish	Italian	French	Japanese
Solutions													
03113027180	3113027180	HC7008	SOL, OPTI- CHECK, TRI- LEVEL	Solution									
03172996180	3172996180	BP7092	OPTI R SNAPPACK	Solution									
Gas utilities													
03112373180	3112373180	BP7001	ASSY, GAS, BOTL, OPTI 1	HarzardousMatl									
General items													
03113353180	3113353180	HP0070	PAPER, TH.PRINTER, ROLL, OPTI CCA	Paper									
03144267001	3144267001	BP7592	Syringe Adapters (30 per box)	Adapter									
03112411180	3112411180	BP7554	SRC - Level 2	Cassette									
03067297001	3067297001	BP7542	Cassette - tHb Calibration	Cassette									
03066762001	3066762001	BP1938	ADAPTER, AMPOULE (150 EACH)										
03113477180	3113477180	MC0024	CAPILLARY TUBES, HEPARINIZED - 200 Ul (250 EACH)										

Global Material No.	Mannheim Material No.	AVL No.	Material Description	Remark	Quantity
Spare Parts, Order As Needed					
03067017001	3067017001	BP7007	ASSY, BATTERY, COMPLETED		
03067688001	3067688001	MC0007	SYRINGE, 12 ML WITH TAPERED T		
03068609001	3068609001	MK0056	BOTL 100 ML NAT. PLAS		
03069338001	3069338001	EX0197	CABLE, POWER, 498/13 2M		
03082695001	3082695001	RE7026	RECEPTACLE, PUMP CARTRIDGE		
03086216001	3086216001	YA5020	STYLET, PROBE, 9110		
03086232001	3086232001	EI7004	SUPPLY, PWR,LOW VOLTAGE, OP		
03104303001	3104303001	BP7025	BATTERY CHARGER, 220 VAC, 47-63 Hz		
03104320001	3104320001	BP7036	BATTERY CHARGER, 110 VAC, 47-63 Hz		
03105261001	3105261001	EX0173	CABLE,PWR, EUROPEAN		
03144224001	3144224001	BP7110	PACK, SHUTDOWN, OPTI R		
03144232001	3144232001	BP7111	CASSETTE, SHUTDOWN, OPTI R		
03027481001	3027481001	BP7118	CARTRIDGE, PERI-PUMP, OPTI R		
03027490001	3027490001	BP7090	ASSY, PRINTER		
03027503001	3027503001	RE7058	SEAL, SMC GAS I/O PORT, OPTI R		
03143538001	3143538001	RE7053	CLOSURE STRIP, FLUID PACK, O		

6.4 Roche OPTI R Analyzer Characteristics

6.5 Roche OPTI R Analyzer

Roche *OPTI R* Analyzer

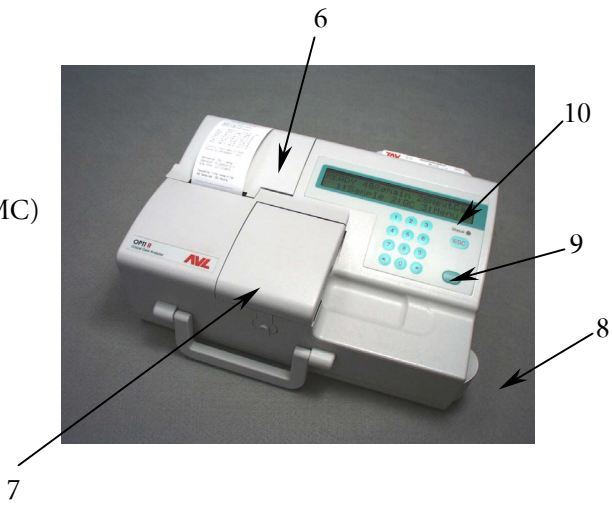
6.5.1 Key Features

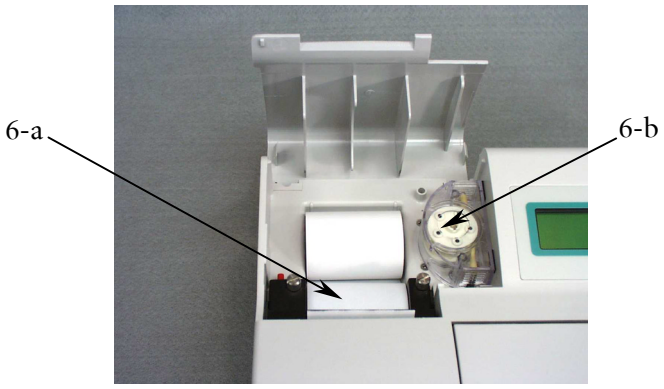
- Room temperature storage of cassettes for up to six months from date of manufacture
- 5 day on-board stability of the cassette
- For greater security, QC lockouts ensure that quality control testing is always performed in accordance with your regulatory requirements.
- Passwords and secure OP ID's provide access to various system functions and limit access of the analyzer only to authorized users.
- Can be battery or AC operated. The rechargeable battery allows independent operation for up to 8 hours
- The calibration gas bottle provides a true gas calibration with each measurement for optimum stability and accuracy. Each gas bottle supplies up to 200 calibrations and is easy to insert into the analyzer.
- User setup option for six (6) languages (English, German, French, Spanish, Italian, Japanese)
- Easy user interface with several setup options and a 14 button keypad
- Very easy handling – minimal training is required
- No sample preparation is required
- Self-contained OPTI R SnapPak provides reagents for multiple tests and serves as a wash and waste reservoir.
- Fast reliable results and printout in approximately 1 minute from sample aspiration
- Sample and control modes of operation – Press "1" for patient sample, "2" for control
- Interface options include RS-232 and IR ports and can be configured for ASCII, ASTM or Mobil-ASTM output (all output fixed at 9600 baud)
- Memory buffer storage can accommodate more than 150 patient results and one months quality control and statistical data
- On-board printer for clear, error-free results reporting
- On-board bar code reader for entry of all lot specific information as well as accession numbers, OP IDs and Pat. IDs.

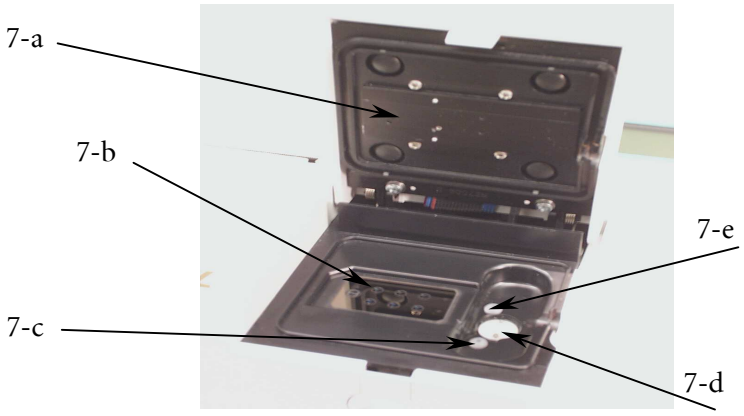
6.5.2 OPTI R Analyzer overview

1) OPTI R Analyzer
2) Battery
3) Printer Paper
4) Power Supply
5) Power Cord (US only)

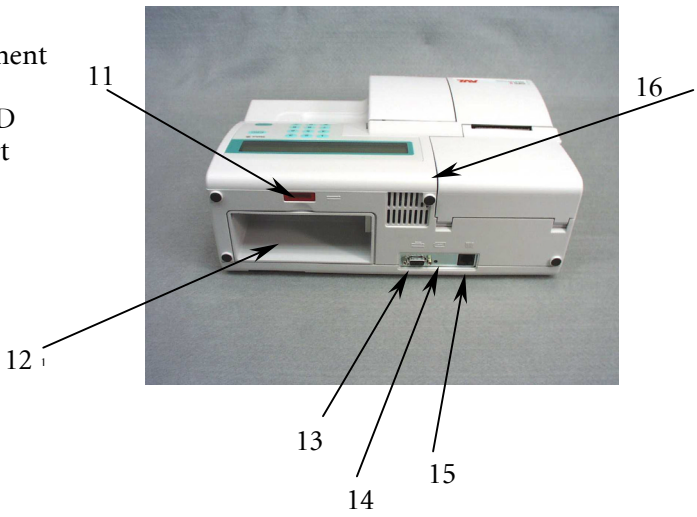
6) Printer / Peristaltic Pump Compartment
   6-a) Printer
   6-b) Peristaltic Pump Cartridge
7) Sample Measurement Chamber (SMC)
   7-a) tHb/SO_2 Cover
   7-b) Optics Lens
   7-c) Outlet Port
   7-d) Cassette Valve Drive
   7-e) Inlet Port
8) Bar Code Reader
9) Key Pad
10) Liquid Crystal Display (LCD)







11) IR Port
12) OPTR R SnapPak Compartment
13) Serial Port
14) Battery Charge Indicator LED
15) Optional Barcode Wand Port
16) Fan



6.5.3 The READY / STATUS Display

```
READY 19Remain 22NextCal
 1:Sample  2:QC 3:Menu >
```

The **READY** display informs the user of important status information such as:

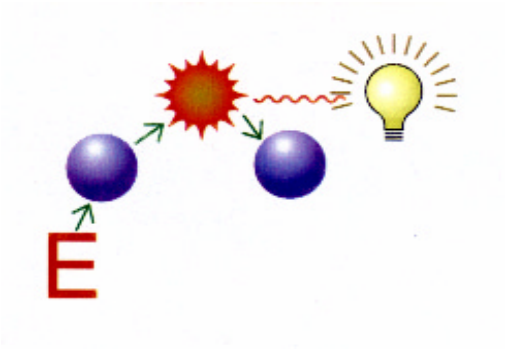
- 19Remain – Number of samples remaining on the cassette (i.e. 19 patient samples remain)
- 22NextCal – Time remaining to the next automatic calibration (i.e. 22 minutes). Resets to 30 minutes after each patient or QC measurement
- 1:Sample – Press "1" to run a Patient Sample.
- 2:QC – Press "2" to run a Quality Control Sample.
- 3:Menu – Press "3" to access the Main Menu.
- You may also view the status of the OPTI R SnapPak, on-board calibration gas bottle or type of cassette currently installed in the instrument. To view the status of these items from the READY display press the right arrow key ">".

```
STATUS: Pack:89% Gas:52%
Type:ECaXX Exp:4day 18hr
```

6.5.4 Technical Principal

6.5.4.1 Sensor Technology

Luminescence is the emission of light energy resulting from excited molecules returning to a resting state. When luminescence is initiated by light, it is commonly referred to as fluorescence. When a fluorescent chemical is exposed to light energy of an appropriate color, electrons in the molecules of the fluorescent chemical are excited.



A very short time later, the electrons return to a resting state and in this process sometimes emit a small amount of light energy. This energy is less than the excitation energy and so has a different color. That is, the emitted light (fluorescence emission), is red-shifted from the excitation light, and is much less intense.

Fluorescent optodes (from **opt**ical electr**odes**) essentially measure the intensity of light emitted from fluorescent dyes. The emitted light is distinguished from the excitation light by means of optical filters. Because the excitation light energy is kept constant, the amount of emission light that results is affected only by the concentration of the analyte. The

concentration of the analyte is determined by calculating the difference in fluorescence measured at a known calibration point and fluorescence measured with the sample's unknown concentration of analyte.

The PO_2 optode measurement principle is based upon luminescence, first documented in the 1930's, and commercially utilized to measure blood PO_2 in 1983. The relationship of luminescence to PO_2 is quantified by the Stern-Volmer equation which describes how the fluorescence emission intensity "I" is reduced as the PO_2 "P" is increased. Unlike conventional electrochemical "Clark" PO_2 electrodes, the oxygen optode does not consume oxygen molecules during the measurement.

$$I_0 / I = 1 + kP$$

The pH optode measurement principle is based upon pH-dependent changes of the luminescence of a dye molecule immobilized in the optode. Such pH indicator dyes have been used by chemists for many years to perform acid-base titrations in turbid media. The relationship of luminescence to pH is quantified by a variant of the Mass-Action Law of chemistry which describes how the fluorescence emission intensity increases as the blood pH is increased above the dye's characteristic pKa. pH optodes do not need a reference electrode to measure pH. However, they exhibit a small sensitivity to the ionic strength of the sample being measured.

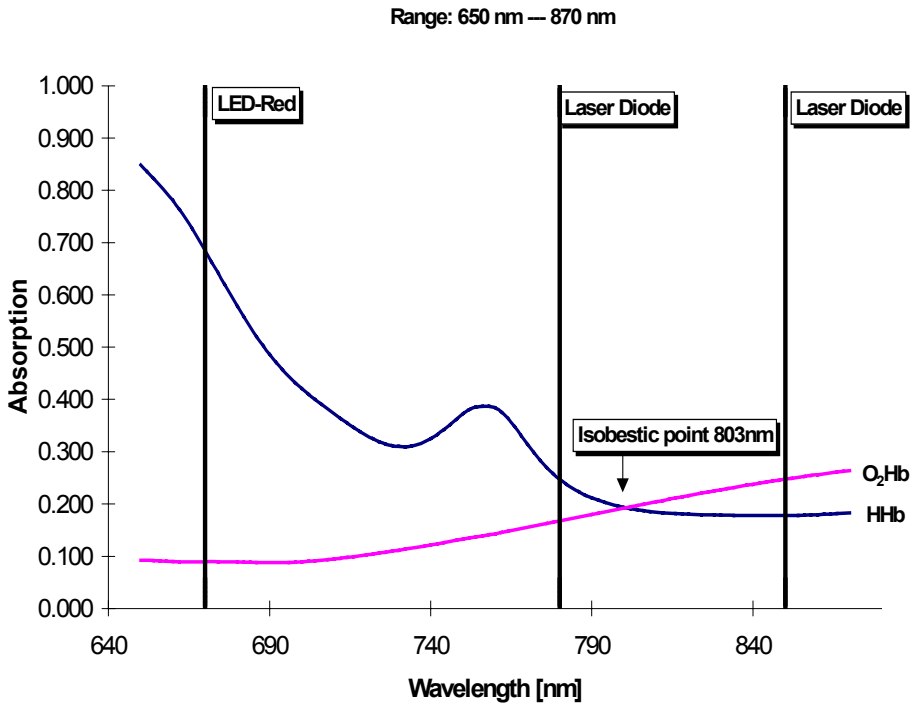
$$I_0 / I = 1 + 10^{pKa-pH}$$

The PCO_2 optode measurement principle is based upon placing a pH optode behind an ion-impermeable membrane, just as conventional PCO_2 blood gas electrodes employ the Severinghaus CO_2 electrode construction. As such, PCO_2 optodes suffer from non-selective interference from volatile acids and bases in blood just as conventional PCO_2 electrodes.

The Na^+, K^+, and Ca^{++} ion optodes are based upon the principle of Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970's to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the Roche OPTI R using the measured pH.

The measurement of total Hemoglobin (tHb) and oxygen saturation (SO_2) uses the well-established principle of optical reflectance. Red and infrared light at three wavelengths is directed at whole, non-hemolyzed blood within a precisely-defined part of the cassette over the O_2 optode. The photons are partially absorbed and reflected by erythrocytes in a manner proportional to hemoglobin level; at low hemoglobin levels the unabsorbed photons strike the O_2 optode's pink overcoat and are reflected back up through the blood a second time. A portion of the reflected light exits the top of the cassette and

is measured by a detector in the instrument. The infrared wavelengths are selected for the hemoglobin measurement because they are largely independent of SO_2, that is, the predominate forms of adult and fetal hemoglobin absorb similarly within the 750-850 nm wavelength range. The red wavelength is utilized for the SO_2 measurement because it is much more strongly absorbed by deoxyhemoglobin than all other hemoglobins, and it is picked close to the isosbestic point for oxy- and carboxyhemoglobin. Sensitivity to erythrocyte aggregation (rouleau formation) is minimized by maintaining high shear force just prior to measurement (see Interferences).

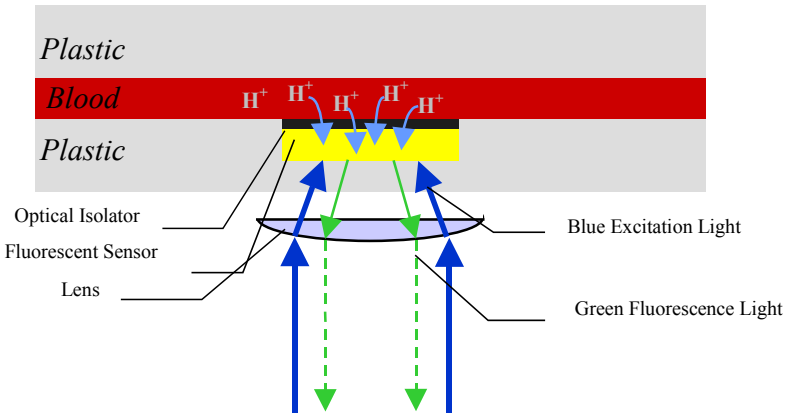


6.5.4.2 Operation

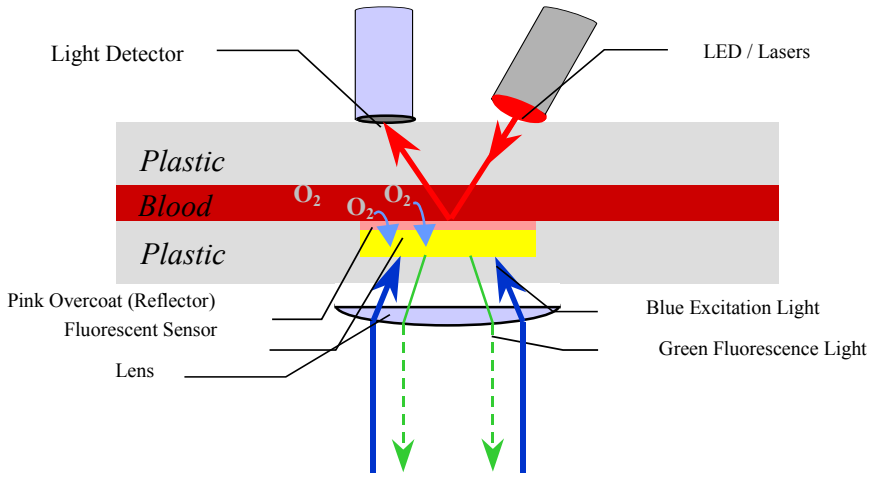
The OPTI R Analyzer is a microprocessor-based instrument measuring optical fluorescence. The sensor cassette contains the sensors, storage buffer and a valve to control the fluid flow. After reading the calibration information specific to a cassette into the instrument by 'swiping' the cassette package through a convenient bar code reader, the cassette is placed in the sample measurement chamber. The analyzer warms the cassette to 37.0 ± 0.1°C, and then performs a calibration verification on the sensors for PCO_2 and PO_2 by passing a gas mixture across the optode sensors. The pH and ion channels are calibrated with precision buffer solution contained in both the sensor cassette and the OPTI R SnapPak. The tHb and SO_2 channels, if configured, are factory-calibrated. When calibration is verified, the analyzer is ready for sampling. During a measurement, the analyzer aspirates the blood sample into the cassette and over the optode sensors and measures the fluorescence emission of the optodes after they have equilibrated with the blood sample. After each measurement, the sample is washed out with buffer from the fluid pack and a one point calibration is

performed, using the calibration gas and the buffer from the OPTI R SnapPak. The blood samples are safely locked away in the waste pouch of the OPTI R SnapPak.

During each measurement, light originating from lamps in the analyzer is passed through optical filters so that photons of a specific color are transmitted to the sensors, causing them to emit fluorescence. The intensity of this emitted light depends upon the partial pressure of oxygen (PO_2), carbon dioxide (PCO_2), hydrogen ion concentration (pH), or electrolyte concentration (Na^+, K^+, Ca^{++}) of the blood in direct contact with the sensors, as described above. The light emitted by the fluorescent sensors is measured by the analyzer after passing through lenses and additional optical components. A filter is used to isolate specific colors of interest from this returning light for measurement by a light detector.



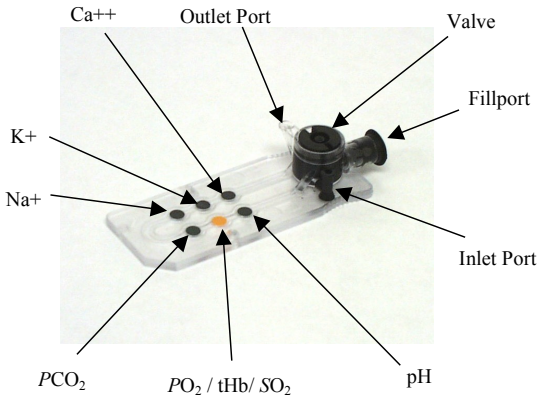
For tHb and SO_2, red and infrared light from three laser diodes is directed via dichroic beamsplitters and optical waveguides onto and through an optically polished window to the blood in the cassette over the O_2 sensor. This light is partially absorbed and reflected by the erythrocytes and sensor overcoat back up into the instrument, traveling via an optical waveguide to a photodiode. The intensity of light reflected back at each wavelength varies in a well-defined way with the blood tHb and SO_2.



The optical signal of the detectors is converted by the microprocessor to a numerical readout in conventional units of measure and displayed on the front of the device. Other clinical parameters commonly used for the assessment of oxygen and acid-base status are calculated from these measured values.

6.5.4.3 The Reusable Sensor Cassette

The sensor cassette shown without the syringe adapter allows for direct sample aspiration from a capillary or Roche Microsampler. The syringe adapter(s) are used when sampling from standard syringes.
Once removed from the storage pouch the cassette must be used within one (1) our or be discarded.



6.5.5 Calibration and Quality Control

6.5.5.1 Calibration

During the measurement and calibration processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cassette. These tests include automatic checks of the cassette for integrity, temperature control, fluidic control during calibration, proper equilibrium behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample during aspiration, and automatic detection of low gas, low battery, dirty optics, or worn pump conditions.

Calibration of the tHb channel is required every 3 months. This calibration is performed using the Roche tHb Calibration Cassette in a manner similar to other instruments that measure tHb and/or hemoglobin derivatives optically. The tHb calibration verifies the measurement optics and electronics and corrects any potential drift. A second HbCal option is available on the OPTI R. The HbCal – LastBlood option allows the OPTI R to be correlated to another tHb measurement method. When the LastBlood is run, the OPTI R will compensate for any measurement bias, allowing any future measured samples to match the alternate device. For more information, including detailed instructions, on the HbCal options, see Section 6.3 “Quarterly Maintenance” in the OPTI R Operator’s Manual.

6.5.5.2 QC Overview

The intent of a Quality Control program is to assure reliable patient values over the clinically significant ranges for all the measured parameters. The program should involve the total process of specimen collection, preparation and results analysis, reporting and interpretation, and the training of personnel involved in all of these processes.

A Quality Control program for blood gas analysis includes the analysis of materials with known values or ranges of expected values and the comparisons of the results from the analyzer with these values. This program allows the analytic performance of a laboratory to be evaluated and documented.

An effective Quality Control program should include:

- Evaluation of precision over the entire analytical range.
- An assessment of failure modes and their effects and means of management, throughout the process.
- Simple statistical calculations which provide a means of assessing precision.
- Control charts or graphs which contain warning limits to assist the technical staff in the evaluation of results.
- A clear set of guidelines to assist the staff in determining if patient results are acceptable.
- A clear set of corrective actions to be taken in "out-of-control" situations.

6.5.5.3 Quality Control

On initial use of a new cassette, validation should be performed by analysis of Roche – Roche blood gas, electrolyte, tHb, and SO_2 controls (Roche OPTI-check) or other equivalent material which has been recommended by Roche. This material should provide target values for pH, PCO_2 , PO_2 , Na^+, K^+, Ca^{++}, tHb and SO_2 over a range of measurement values typically seen in each laboratory. The results obtained should fall within limits defined by the day-to-day variability as measured in the user's laboratory. Additionally, it is recommended to run two levels of (OPTI-check) controls every shift or at a minimum every 24 hours.

It is recommended to aspirate Quality Control and Proficiency testing material directly from the ampoule. This procedure helps to minimize sensitivity to pre-analytic and other errors associated with the use of aqueous controls (see Limitations Section).

All specific performance specifications reported in this Summary are determined from the above, minimal recommendations for quality control verification.

Every hospital is required to develop its own policies and procedures for quality control checks. Minimum guidelines are defined by a variety of regulatory agencies. For agencies requiring a liquid QC material, OPTI-check is available.

OPTI-check is a specially formulated aqueous liquid control material that controls all analytes measureable by the OPTI R. It contains a stable suspension of polystyrene microbeads which reflect and partially absorb red and infrared light similarly to erythrocytes, allowing true measurement of tHb and SO_2. The three control levels contain three different concentrations of microbeads to simulate low, medium, and high hematocrit blood samples. OPTI-check provides a method of performing daily QC checks for laboratories selecting to measure liquid QC material.

6.5.5.4 Calibration Verification

Calibration verification allows for the validation of the blood gas analyzer's ability to recover known values at various points within the reportable range of all parameters and may be required by various regulatory agencies.

The OPTI R Method Sheet, included in the front section of the OPTI R Operator's Manual, provides precision and recovery data for all the measured parameters in the ranges that are usually encountered in the diagnostic testing of patients.

Should a laboratory wish to perform a calibration verification for measurement values outside the broad range, Roche suggests tonometry of whole blood for PO_2 and PCO_2, correlation against flame photometry for electrolytes, correlation against cyanmethemoglobin method for tHb, and blood pH correlation with conventional blood gas analyzers.

6.5.5.5 QC Recommendations

Policies regarding the measurement of QC samples are established by the individual hospital. Roche recommends that QC solutions be run, as a minimum, with each new cassette and once every shift or every 24 hours thereafter. You should use only Roche recommended controls such as OPTI-check which do **NOT** contain dye or other colored material. Whenever a new lot of controls is opened, be sure to enter the lot number information into the analyzer as described in Chapter 3 "Customization" of the OPTI R Operator's Manual. These materials should provide target values for pH, PCO_2, and all other measured parameters over a range of measurement values typically seen in each testing site laboratory. The results obtained should fall within limits defined by the day-to-day variability as measured in the user's laboratory facility.

Roche recommends the use of **noncolored pH/blood gas/electrolyte control** containing scattering particles for tHb control for routine evaluation of imprecision as a part of an effective quality control program.

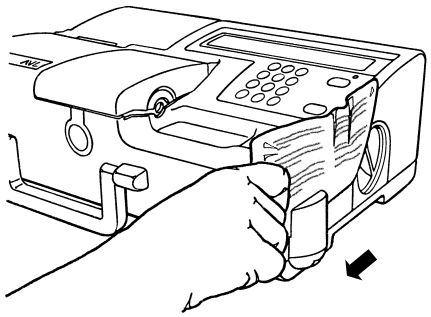
6.5.6 General Procedure for Measurements

All stages of the procedure are menu-driven, that means, the operator is prompted through all steps via the liquid crystal display. All user input and response are entered via the numeric keypad or barcode reader when applicable.

6.5.6.1 Calibration/Barcode(s)

Each lot of OPTI R cassettes is calibrated during the manufacturing process. The calibration is performed using high precision standard solutions and gravimetrically-prepared gas mixtures to determine the cassette's measurement characteristics at multiple points within the analyte's measurable range. Every cassette package is then labeled with two bar codes (A and B) which contain this calibration information, as well as its lot number and expiration date.

For each new cassette the cassette's bar code's are read into the analyzer by 'swiping' the cassette package through a conveniently located bar code reader. The cassette is then installed and a calibration verification is performed using a precision gas mixture and the cassette's internal storage buffer, in a manner similar to other combined blood gas / ion analyzers. In addition, an optical zero point calibration of all optical channels is performed.



Swiping a new cassette through the bar code reader

6.5.7 Specimen Collection and Handling

6.5.7.1 Safety

Universal precautions must be observed when collecting blood specimens. It is recommended that all blood specimens be handled as if capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), or other bloodborne pathogens. Proper blood collection techniques must be followed in order to minimize risk to the laboratory staff, and gloves should be worn. Please refer to NCCLS document M29-T2, *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue - Second Edition;* Tentative Guideline for further information on safe handling of these specimens.

6.5.7.2 Sample Requirements

Refer to NCCLS document H11-A2, *Percutaneous Collection of Arterial Blood for Laboratory Analysis - Second Edition*; Approved Standard, May 1992, for detailed information on sample collection, storage and handling.

Blood sampling for analysis must be performed under proper medical supervision with details of collection, including sampling devices, site selection, sample handling documentation and specific procedures used approved by the personnel responsible.

6.5.7.3 Anticoagulants and Sample Collection Devices

Lithium heparin is the only acceptable anticoagulant for blood gas **and** electrolyte analysis. Lithium heparin, sodium heparin or balanced heparin salts are the only acceptable anticoagulants for blood gas analysis. Other anticoagulants such as EDTA, citrate, oxylate and fluoride have a significant effect on blood pH and electrolyte levels and should not be used. Lithium heparin should not be used for samples taken also for analysis of lithium.

6.5.7.3.1 Syringes

If liquid heparin is used as an anticoagulant, collection devices should be no larger than the amount of blood required to minimize the effects of dilution of the blood by the anticoagulant solution. Although plastic syringes are commonly used for collection of blood specimens for blood gas analysis, there have been reports in literature regarding the use of plastic syringes when PO_2 values higher than normal are expected. Particular attention should be paid to cooling blood samples in ice water, because of the CO_2 and oxygen solubility in some plastics. If blood specimens are expected to have very high PO_2 values, care should be taken to analyze the specimen as quickly as possible following collection to avoid the need for cooling. *Attention should be paid to thorough mixing of whole blood samples prior to analysis, since sedimentation of blood cells affects the measurement of total hemoglobin.*

6.5.7.3.2 Capillary Tubes

Capillary blood specimens should be collected using capillary tubes which have a minimum volume, filled, of 125 µL. The Roche (Roche Reference Number 03113477180) Capillary Tube is ideally suited with a minimum volume, filled, of 200 µL. The Roche capillary tubes for pH, blood gas, and electrolyte analysis should not be used for samples taken for the analysis of lithium.

Samples may be collected in capillary tubes after warming the area or otherwise stimulating it to promote arterial circulation before the puncture. The puncture should be made deeply enough to ensure a free and rapid flow of blood.

Do not use clay-capped capillary tubes as the rough, broken edge left when the capillary is cut may cause damage to the OPTI R cassette fill port. Use only capillary tubes with fire-polished ends to prevent damage to the cassette. If a mixing flea is used, as required in some capillary tubes, take care to remove the flea prior to sample introduction to avoid damage to the cassette.

Specimens collected in capillary tubes are stable at room temperature for up to 30 minutes after collection because of the rapid cooling of the sample accomplished during filling.

6.5.7.3.3 Roche Microsamplers

Blood may be collected for analysis on the OPTI R with the Roche Microsampler to provide two filled capillary tubes.

After collection, the Microsampler should be capped and transported in a horizontal position to the instrument for analysis within 30 minutes, as with all specimens collected in capillary tubes.

6.5.7.4 Handling and Storage of Samples

Please refer to NCCLS Document C27-A, *Blood Gas Pre-Analytical Considerations: Specimen Collection, Calibration and Controls*; Approved Guideline, April 1993 for a detailed discussion of guidelines for the collection of acceptable specimens, instrument calibration, and quality control in pH and blood gas analysis; including details of many potential sources of error which may cause inaccurate results.

Whole blood samples should be collected in a heparinized syringe, Roche Microsampler or capillary and analyzed as soon as possible after collection. Immediately after collection, check the syringe or other device for air bubbles and carefully expel any trapped bubbles, following the manufacturer's recommended procedure. Extreme caution should be used to avoid needle stick injury. If collected in a syringe or vacuum tube, mix the specimen thoroughly with anticoagulant by gentle inversion or by rolling the syringe between both hands. Properly identify the specimen, following usual procedures for such documentation. Place the syringe containing the specimen in an ice slurry. Blood gases, pH and glucose content will change if the specimen remains at room temperature in a syringe for more than 5 minutes due to cellular metabolism.

PO_2 changes due to oxygen consumption may be influenced by several factors, including: white blood cell count, reticulocyte count, storage temperature and initial PO_2 value. At storage temperatures of 1 to 5 °C, the results obtained from the specimen are valid up to 2 hours. Samples expected to have high white blood cell count, reticulocyte count, or high PO_2 values should be analyzed as soon as possible after collection.

Erythrocyte aggregation and sedimentaton may occur very quickly in syringes containing pathologic blood samples and may adversely affect the measurement of *c*tHb in any analyzer. To prevent such errors, first insert the OPTI R cassette into the analyzer to initiate calibration. Next, mix the syringe sample well by rolling the syringe for at least 60 seconds, after expelling any trapped bubbles, then immediately measure in the OPTI R.

The OPTI R system aspirates blood in the same manner from syringes, capillaries, or the Roche Microsampler. No changes are made to the aspiration rate, volume or timing. Therefore, there are no biases or

imprecision dependent upon the sample introduction method. Sufficient volume must, however, be present in syringes (0.25 mL in a 1 mL syringe) to prevent mechanical interference between the syringe plunger and the OPTI R syringe adapter.

Errors in blood analysis on properly collected samples may result from improper mixing of the sample after collection and before measurement; contamination with room air resulting from failure to expel any trapped bubbles after collection; and from metabolic changes in the sample.

6.5.8 Handling Steps:

The Roche OPTI R Analyzer is fast and easy to operate. Whenever **READY** appears on the display, the unit is ready to perform a sample measurement.

```
READY 19Remain 22NextCal
 1:Sample 2:QC 3:Menu  >
```

1. Press "1" to start the patient measurement sequence.

```
Mix and place the    XXX
 Sample - Press <ENTER>
```

2. The display will then prompt you to mix and place the sample. Mix the syringe sample will by rolling it between the palms of your hands and inverting end over end.

NOTE: Sedimentation of blood cells causes alteration of tHb values. Therefore mix the sample well just prior to analysis.

3. Using a capillary, a syringe and adapter, or an Roche Microsampler, attach the sample to the cassette fillport and press <ENTER>. The sample is then aspirated. (The sample is then measured. During the measurement the status light is blinking and a countdown of the measuring time remaining is displayed in the right hand corner of the screen.

```
Aspirating Sample
   Please Wait
```

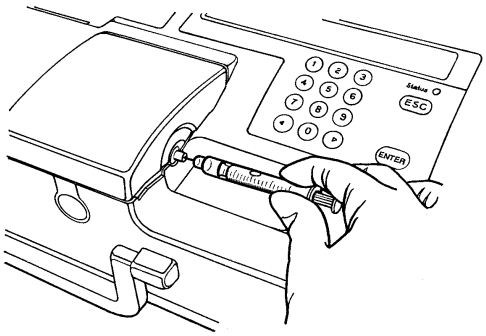
```
Measuring Sample
```

NOTE: When sampling from syringes always use a new syringe adapter.

NOTE: If using a syringe, make sure the syringe adapter is not touching the syringe adapter.

Attach Capillary Sample

Attach Syringe Sample



4. Remove the sample when prompted and press <ENTER>.

```
Measuring Sample     XXX
Remove Sample    <ENTER>
```

NOTE: Failure to remove the sample may cause wash errors.

5. To enter patient information, press <ENTER> when this display appears. You will then be prompted through entering patient demographic information which has been selected under SETUP. (See the OPTI R Operator's Manual for complete list of patient demographics available).

```
Measuring - To Input XXX
Pat. Data press  <ENTER>
```

NOTE: You may also press the < left arrow key when this display appears to recall the patient information that was entered during the previous patient sample. Then press <ENTER> to edit this information.

NOTE: Parameter blanking may also be available depending on the analyzer configuration under Setup (See the OPTI R Operator's Manual for parameter blanking and disabling under Setup).

6. When the analysis is completed, the status light stops blinking and the instrument alerts you that the measurement has been completed with a Beep'. At this time you may continue entering or editing the patient information, until you have completed or display the results immediately by pressing <ESC> at any time.

```
   pH     PCO2    PO2    BE
 7.388    44.6   146.9   0.8
```

NOTE: If the keypad has not been touched for approximately three (3) minutes the results will automatically be displayed.

7. The 4th column displays the calculated parameters. By pressing the < or > keys all calculated parameters can be viewed.

NOTE: If patient temperature was input, it will be displayed in place of a calculated parameter. In this case, the blood gas values displayed are temperature corrected.

NOTE: The calculated parameter first shown with the result may be configured in the setup menu. (See the OPTI R Operator's Manual for configuration under Setup).

8. Press <ENTER> to display the second set of results with their associated calculated parameters.

```
  Na+    K+     Ca++    tCO2
 156.4   5.82   1.24    22.1
```

9. Press <ENTER> again to display the third set of results, and calculated parameters.

```
  PO2    tHb    SO2    Hct(c)
 146.9   15.2   99.5   45.6
```

NOTE: The resolution of the measured parameters may be configured 'HIGH'(Na+ = 156.4 mmol/L) or "LOW" (Na+ = 156 mmol/L) in the setup menu (See the OPTI R Operator's Manual for configuration under setup).

NOTE: The OPTI R Analyzer "flags" values that are above or below the programmed ranges with an up or down arrow. If the value is outside the measurable range a 'High' or 'Low' will be displayed and a > or < with a range printed out on the patient report.

```
For Ready press     <ESC>
Edit Pat. Data    <ENTER>
```

10. Press <ESC> to go to the next sample. To edit the patient data press <ENTER>. If the wash cycle is not finished yet, a short "Please Wait" will be displayed before returning to READY.

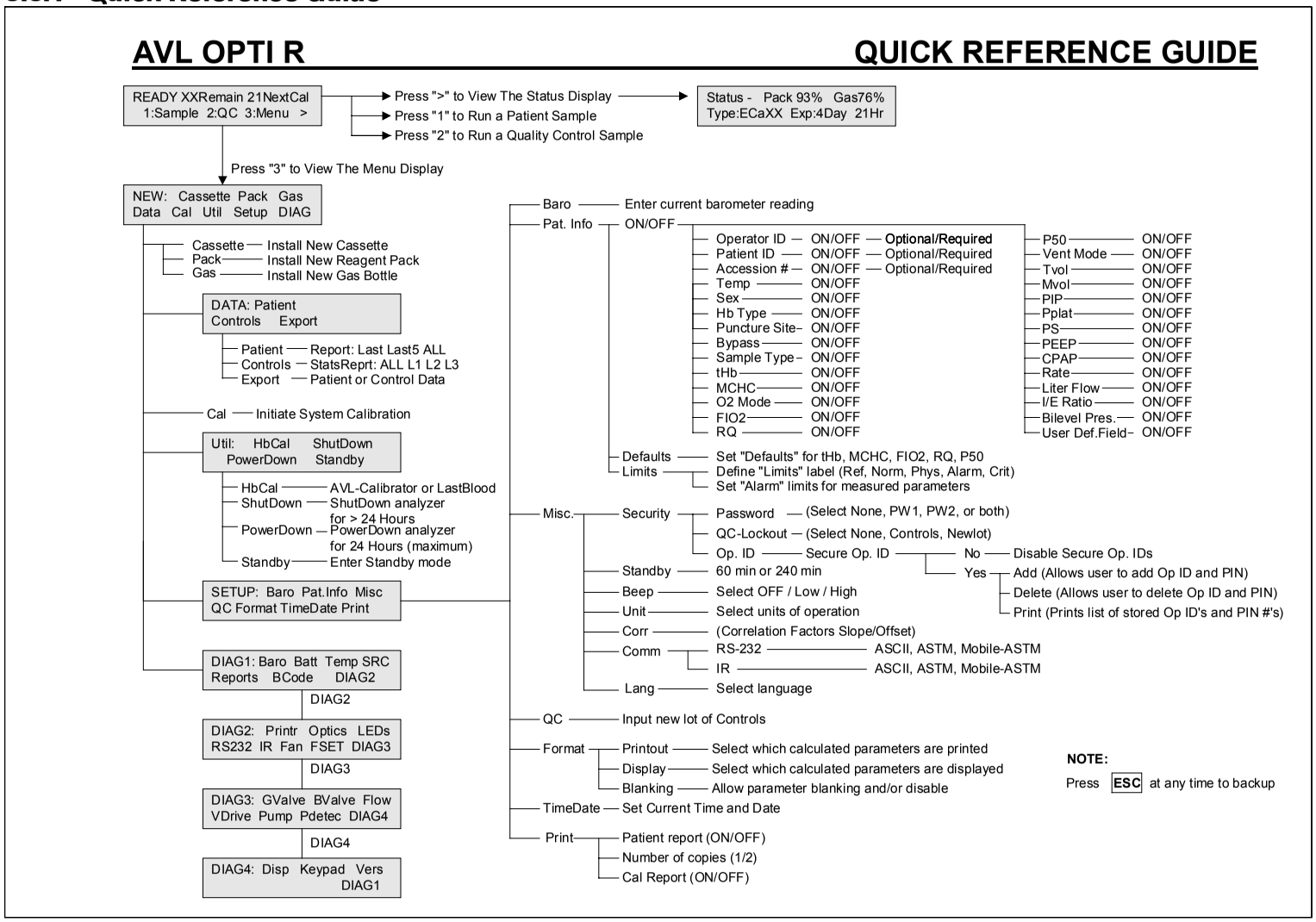
NOTE: For minimal keystrokes, press <ESC> when the first results are displayed.

NOTE: The printout will automatically start when the first results are displayed. This feature "Printing the Report" may be turned off in setup (See the OPTI R Operator's manual for configuration under Setup).

```
READY 18Remain 30NextCal
 1:Sample  2:QC 3:Menu >
```

6.6 Software Overview/Quick Reference Guide

6.6.1 Quick Reference Guide


AVL OPTI R
QUICK REFERENCE GUIDE
READY XXRemain 21NextCal
1:Sample 2:QC 3:Menu >
Press ">" to View The Status Display
Press "1" to Run a Patient Sample
Press "2" to Run a Quality Control Sample
Status - Pack 93% Gas76%
Type:ECaXX Exp:4Day 21Hr
Press "3" to View The Menu Display
NEW: Cassette Pack Gas
Data Cal Util Setup DIAG
Cassette — Install New Cassette
Pack — Install New Reagent Pack
Gas — Install New Gas Bottle
DATA: Patient
Controls Export
Patient — Report: Last Last5 ALL
Controls — StatsReprt: ALL L1 L2 L3
Export — Patient or Control Data
Cal — Initiate System Calibration
Util: HbCal ShutDown
PowerDown Standby
HbCal — AVL-Calibrator or LastBlood
ShutDown — ShutDown analyzer for > 24 Hours
PowerDown — PowerDown analyzer for 24 Hours (maximum)
Standby — Enter Standby mode
SETUP: Baro Pat.Info Misc
QC Format TimeDate Print
DIAG1: Baro Batt Temp SRC
Reports BCode DIAG2
DIAG2
DIAG2: Printr Optics LEDs
RS232 IR Fan FSET DIAG3
DIAG3
DIAG3: GValve BValve Flow
VDrive Pump Pdetec DIAG4
DIAG4
DIAG4: Disp Keypad Vers
DIAG1
Baro — Enter current barometer reading
Pat. Info — ON/OFF
Operator ID — ON/OFF — Optional/Required
Patient ID — ON/OFF — Optional/Required
Accession # — ON/OFF — Optional/Required
Temp — ON/OFF
Sex — ON/OFF
Hb Type — ON/OFF
Puncture Site — ON/OFF
Bypass — ON/OFF
Sample Type — ON/OFF
tHb — ON/OFF
MCHC — ON/OFF
O2 Mode — ON/OFF
FIO2 — ON/OFF
RQ — ON/OFF
P50 — ON/OFF
Vent Mode — ON/OFF
Tvol — ON/OFF
Mvol — ON/OFF
PIP — ON/OFF
Pplat — ON/OFF
PS — ON/OFF
PEEP — ON/OFF
CPAP — ON/OFF
Rate — ON/OFF
Liter Flow — ON/OFF
I/E Ratio — ON/OFF
Bilevel Pres. — ON/OFF
User Def.Field — ON/OFF
Defaults — Set "Defaults" for tHb, MCHC, FIO2, RQ, P50
Limits — Define "Limits" label (Ref, Norm, Phys, Alarm, Crit)
Set "Alarm" limits for measured parameters
Misc. — Security — Password — (Select None, PW1, PW2, or both)
QC-Lockout — (Select None, Controls, Newlot)
Op. ID — Secure Op. ID — No — Disable Secure Op. IDs
Yes — Add (Allows user to add Op ID and PIN)
Delete (Allows user to delete Op ID and PIN)
Print (Prints list of stored Op ID's and PIN #'s)
Standby — 60 min or 240 min
Beep — Select OFF / Low / High
Unit — Select units of operation
Corr — (Correlation Factors Slope/Offset)
Comm — RS-232 — ASCII, ASTM, Mobile-ASTM
IR — ASCII, ASTM, Mobile-ASTM
Lang — Select language
QC — Input new lot of Controls
Format — Printout — Select which calculated parameters are printed
Display — Select which calculated parameters are displayed
Blanking — Allow parameter blanking and/or disable
TimeDate — Set Current Time and Date
Print — Patient report (ON/OFF)
Number of copies (1/2)
Cal Report (ON/OFF)
NOTE:
Press ESC at any time to backup

Running Patient Samples

READY XXRemain 21NextCal 1:Sample 2:QC 3:Menu >	Press "1"

NOTE: Make sure the sample is free of trapped gas bubbles and completely mixed, by rolling the syringe between the palms of your hands and inverting end over end for at least one minute.

NOTE: When sampling from syringes - Be sure to use a new syringe adapter with each sample.

Mix and place the XXX Sample - press <ENTER>	(place sample) Press Enter
Aspirating Sample Please Wait	
Measuring Sample	
Measuring Sample XXX Remove Sample <ENTER>	(remove sample) Press Enter
Measuring - To input XX Pat.Data press <ENTER>	Press enter to input Patient Data
pH PCO2 PO2 BE 7.399 45.6 99.6 2.1	Press Enter (printout begins)
Na+ K+ Ca++ tCO2 144.4 4.91 1.23 28.9	Press Enter
PO2 tHb SO2 Hct(c) 99.6 19 98.7 57.06	Press enter
For READY press <ESC> Edit Pat.Data <ENTER>	For READY press ESC Press Enter to Edit Patient. Data

Running Quality Control OPTI-check

READY XXRemain 21NextCal 1:Sample 2:QC 3:Menu >	Press "2"
Run Controls Op ID: XXXXXXXXXX	Enter OP ID (If required) Press Enter
Run Controls Level: 1 2 3	(select Level 1, 2 or 3) Press Enter
Control Level 2 XXXX To confirm press <ENTER>	(confirm Level/Lot) Press Enter
Place Control XXX and press <ENTER>	(place control) Press Enter
Aspirating Control Please Wait	
Measuring Control	
Measuring Control XXX Remove Control <ENTER>	(remove control) Press Enter
Measuring Control XXX	
pH PCO2 PO2 Test 7.402 44.0 101.6 PASS	Press Enter
Na+ K+ Ca++ Test 144.6 4.91 1.24 PASS	Press Enter
PO2 tHb SO2 Test 101.6 14.3 88.7 PASS	Press Enter (printout begins)
Control Results: PASS Accept Rej/Edit Review	Press Enter to Accept or select Rej/Edit or Review

READY / STATUS Display

Time remaining to next calibration (minutes)
Patient Samples remaining on cassette

READY XXRemain 21NextCal
1:Sample 2:QC 3:Menu >

Gas bottle volume remaining (%)
Reagent SnapPak volume remaining (%)

STATUS - Pack 93% Gas76%
Type:ECaXX Exp:4Day 21Hr

Current cassette type installed
Time remaining on cassette (days/hours)

MAINTENANCE

Weekly

- Clean Sample Measurement Chamber (SMC) - Both optic lens and inside top cover

Every 3 Months

- Perform tHb Calibration using the AVL-Calibrator

Every 6 Months

- Replace peristaltic pump cartridge, receptacles and SMC I/O ports

As Needed

- Clean exterior surfaces
- Replace Cassette
- Replace Reagent
- SnapPak
- Replace Gas Bottle
- Replace Printer Paper
- Deep Discharge Battery (disconnect from AC power and leave on overnight)
- Recharge Battery (In unit for 6 hours or in optional charger)

6.6.2 Internal Memory Functions

The OPTI R Analyzer has the following memory functions:

The buffer-capacity of the OPTI R allows for >150 patient results to be stored in memory along with all pertinent patient demographics which were entered during the measurement.

The buffer-capacity of the OPTI R allows for 1 month of three (3) levels of quality control data to be stored in memory.

The buffer-capacity of the OPTI R allows for 150 patient ID's and 150 associated 4-digit PIN numbers to be stored in memory

6.6.2.1 Overall Test Time

Time To Result (after sample aspiration):	Approximately one (1) minute to one (1) minute and fifteen (15) seconds after sample aspiration
Wash and Calibration:	Approximately two (2) minutes
Overall Cycle Time:	Approximately three (3) minutes to three (3) minutes and fifteen (15) seconds

6.6.2.2 Using Patient Identification Numbers

Patient identification numbers ensure an unambiguous identification of results and patient samples. The OPTI R Analyzer is designed for entering patient identification numbers (referred to as Pat. IDs in the following). The entry may be set to optional or required, which means this function may be enabled in the setup menu if required. A numerical Pat. ID may be entered either directly on the instrument using the numeric keypad, on-board bar code reader, or by means of an optional external bar code wand connected to the port on the rear of the instrument. The length of the Pat. ID may be entered in a range of 1 and 15.

A Pat. ID. may be entered either during or after the measurement is completed, it is not possible to define a Pat. ID for that result after the result has been stored to the internal memory.

6.6.2.3 Using Operator Identification Numbers

Operator identification numbers ensure an unambiguous identification of results and patient samples. The OPTI R Analyzer is designed for entering operator identification numbers (referred to as Op.-IDs in the following).

Entry can be configured to be optional or required under the setup menu. A numerical Op.-ID may be entered either directly on the instrument using the numeric keypad, on-board bar code reader or by means of an optional external bar code wand connected to the port on the rear of the instrument. The length of the Op.-ID may be entered in a range of 1 and 10.

An Op.-ID may be entered either during or after the sample measurement depending on the instrument configuration under setup.

Secure Op.-ID's allow the facility to "lock-out" unauthorized users from operating the analyzer. With Secure OP ID's activated under Setup the administrator may store up to 150 unique operator identification numbers in memory, each with an associated 4-digit PIN number. At the time of operation the user is prompted to enter their unique 4-digit PIN however, it is the associated operator identification number (not the PIN) which is shown on the printout. This feature offers true security.

6.6.2.4 Using Accession Numbers

Accession numbers ensure an unambiguous identification of results and patient samples. The OPTI R Analyzer is designed for entering accession numbers (referred to as ACC#'s in the following).

Entry can be configured to be optional or required under the setup menu. A numerical accession number may be entered either directly on the instrument using the numeric keypad, the on-board bar code reader or by means of an optional external bar code wand connected to the port on the rear of the instrument. The length of the accession number may be entered in a range of 1 and 11.

6.6.3 OPTI R Analyzer – Technical Data

Measured Parameters	Range	Resolution
pH	6.6 to 7.8 pH units	0.001 pH units
PCO_2	10 to 200 mmHg	0.1 mmHg
PO_2	10 to 700 mmHg	0.1 mmHg
Na^+	100 to 180 mmol/L	0.1 mmol/L
K^+	0.8 to 10 mmol/L	0.01 mmol/L
Ca^{++}	0.2 to 3.0 mmol/L	0.01 mmol/L
ctHb	5 to 25 g/dL	0.1 g/dL
SO_2	60 to 100 %	0.1 %
Barometric Pressure	300 to 800 mmHg	

Calculated Parameters

Actual bicarbonate (HCO_3^-)	1.0 to 200.0 mmol/L
Base excess (BE)	-40 to +40 mmol/L
Base excess (BE_{ecf})	-40 to +40 mmol/L
Base excess actual (BE_{act})	-40 to +40 mmol/L
Buffer bases (BB)	0.0 to 100.0 mmol/L
Total CO2 (tCO_2)	1.0 to 200.0 mmol/L
Standard bicarbonate ($st.HCO_3^-$)	1.0 to 200.0 mmol/L
Standard pH (st. pH)	6.500 to 8.000
Oxygen saturation (SO_2)	0.0 to 100.0%
Oxygen content (O_2ct)	0.0 to 56.0 mL/dL
Hematocrit (Hct (c))	15 to 75%
Hydrogen ion concentration (cH^+)	10.0 to 1000.0 mmol/L
Alveolar-arterial oxygen partial pressure difference ($AaDO_2$)	0.0 to 800.0 mmHg
P50	15.0 to 35.0 mmHg
Standardized ionized Calcium (nCa^{++})	0.1 to 3.0 mmol/L

Operating Parameters

Minimum Sample Size	125µL
Sample Type	Whole blood, serum, plasma, aqueous for QC
Sample Application	Syringe, Capillary or Microsampler
Sample Input	Automatic aspiration
Analysis Time (time to result)	Approximately 1 minute from sample aspiration
Ambiant Temperature	10 °C – 30 °C (50 °F - 86 °F)
Relative Humidity	5% - 95% (non-condensing)
Measurement Principle	optical fluorescence, for tHb/SO2 optical absorbance/reflectance

Input Values

Operator identification number	Blank to 9999999999
Patient identification number	Blank to 999999999999999
Accession number	Blank to 99999999999
Patient temperature	14 °C – 44 °C (58 °F – 111 °F)
Patient sex	male, female or ?
Hemoglobin type	adult / fetal
Puncture site	LR/RR/LB/RB/LF/RF/Cord/Scalp Where: LR = Left Radial RR = Right Radial LB = Left Brachial RB = Right Brachial LF = Left Femoral RF = Right Femoral Cord = Cord Scalp = Scalp
Bypass	Off Pump / On Pump
Sample type	Art/Ven/MixVen/Cap/Cord/CPB Where: Art = Arterial Ven =Venous MixVen =Mixed Venous Cap = Capillary Cord = Cord CPB = Cardio-Pulminary Bypass
total hemoglobin, tHb	1-26 g/dL / 1-260 mg/dL / 1-16 mmol/L
Mean corpuscular hemoglobin concentration (MCHC)	29.0 – 37.0 %
O2 Mode	RmAir/Mask/T-P/NC/Vent/Bag/Hood/Other Where: RmAir = Room Air Mask = MAsk T-P = T-Piece NC = Nasal Canula Vent = Ventilator Bag = Bag (manual resuscitation) Hood = Hood Other = Other
FIO2	0.21 – 1.0
Hemoglobin (tHb)	1 – 16 g/dL
respiratory quotient, RQ	0.70 – 2.00
P50	15 – 40 mmHg (2.0 – 5.3 kPa)

Input Values

Vent Mode	No/SIMV/PSV/PCV/CMV-AC/CPAP/PCIVR/BIPAP Where: No = None SIMV = Syncronized Intermittent Mandatory Ventilation PSV = Pressure Support Ventilation PCV = Pressure Control Ventilation CMV-AC = Controlled Mechanical Ventilation / assist Control CPAP = Continuous Positive Airway Pressure PCIVR = Pressure Control Inverse Ratio BIPAP = Bi-Level Positive Airway Pressure
Tidal Volume, TVol (VT)	0 – 4000
Minute Volume, MVol (VE)	0 – 120
Peak Inspiratory Pressure, PIP	0 – 140
Plateau Pressure, Pplat	0 – 100
Pressure Support Value, PS	0 – 99.9
Positive End Expiratory Pressure, PEEP	0 – 50
Continuous Positive Airway Pressure, CPAP	0 – 50
Rate (f)	0 – 155
Flow Rate, Liter Flow (FR)	000.00 – 300.00
Inspiratory / Expiratory Ratio, I/E Ratio	0.2 – 9.9 / 0.2 – 9.9
BiLevel Pressure	0 – 9.9 / 0 – 9.9 cmH_2O
User Defined Field	Blank to 999999

6.6.4 Peripheral equipment (optional)

6.6.4.1 Battery Charger (110volts)

For fast charging of extra battery pack for the OPTI R Analyzer. Each chardger contains a power supply with circuitry. Input voltage 110 VAC, 47 – 63 Hz.

The following battery charger, which has to be ordered separately, can be used:

Roche Diagnostic Corporation
235 Hembree Park Drive
Roswell, Georgia 30076
Roche Reference Number - 03104320001

6.6.4.2 Battery Charger (220volts)

For fast charging of extra battery pack for the OPTI R Analyzer. Each charger contains a power supply with circuitry. Input voltage 220 VAC, 47 – 63 Hz.

The following battery charger, which has to be ordered separately, can be used:

Roche Diagnostics Corporation
235 Hembree Park Drive
Roswell, Georgia 30076
Roche Reference Number - 03104303001

6.6.4.3 External Barcode Wand

The following External Barcode Wand, which has to be ordered separately, can be used:

Roche Diagnostics Corporation
235 Hembree Park Drive
Roswell, Georgia 30076
Roche Reference Number – 03133516001

If connecting a bar code reader to the OPTI R Analyzer other than the type described above, data transmission problems may occur.

6.6.4.4 Cable Interface, OPTI R Analyzer to PC

The following Cable Interface, OPTI R Analyzer to PC, which has to be ordered separately, can be used:

Roche Diagnostics Corporation
235 Hembree Park Drive
Roswell, Georgia 30076
Roche Reference Number – 03133524001

6.6.5 Data Manager/PC Connection

It is possible to connect a Host-/PC to the OPTI R Analyzer. Once the measurement is complete the result is automatically transmitted including all available information such as date, time, Pat.-ID, Op.-ID, additional patient demographics and measurement results. For this purpose, the Host-/PC connection must be configured under the setup menu.

The Host-/PC is connected via wireless transmission (IR Port) or the standard serial port by means of an RS-232C cable with three (3) data lines. For further details please refer to the OPTI R Operator's Manual.

6.6.6 Quality aspects / Instrument Self Check

Standard settings are done by Roche during the manufacturing process. Internal checks are automatically accomplished each time a new cassette, SnapPak or gas bottle is installed. Further verification of the system is done during the measurement, wash and calibration phase of the overall sampling cycle.

For routine check's of the system performance control material can be ordered by the customer (OPTI-check Quality Control Material) in order to check whether the system (Analyzer and Cassette) gives results that are within a certain target range.

6.6.6.1 General Information on Error Detection and Correction

The OPTI R has a user-friendly design. Following all instructions given in the Operator's Manual should therefore prevent that errors occur. Should, however, an error occur, the customer should follow the instructions given in the OPTI R Operator'' Manual. If, in spite of this, an error cannot be corrected Roche Service has to be contacted.

6.6.7 Consumables

6.6.7.1 Calibration Gas

Roche Reference Number - 031123731880

Use:	For calibration of pH, PCO_2, PO_2, in the Roche OPTI R Critical Care analyzer	
Contents:	Each disposable, low pressure cylinder contains approximately 2 liters of gas (at less than 145 psi at 21 °C)	
Composition:	Oxygen	14.0 ± 0.02%
	Carbon Dioxide	6.0 ± 0.02%
	Nitrogen	balance
Storage:	Refer to package labeling	

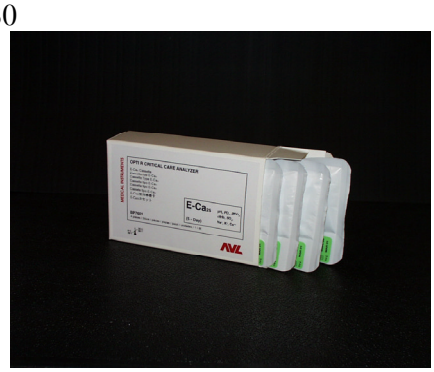
6.6.7.2 OPTI R SnapPak

Roche Reference Number - 031123731880

Use:	For washing and calibrating cassette and waste containment for OPTI R Analyzer
Contents:	180mL of buffer solution
Composition:	Aqueous HEPES-bicarbonate buffer solution with biocides
Storage:	Refer to package labeling

6.6.7.3 OPTI R Cassette, E-Ca25 Type

Roche Reference Number - 03133532180



Use:	For measurement of pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb and SO_2 with the OPTI R Critical Care Analyzer. Each cassette provides 25 patient samples or 5 day(s) of in use operation.
Contents:	Each package contains an insert sheet and four (4) cassettes. Each plastic cassette contains buffer and optical sensors.
Composition:	Aqueous HEPES-bicarbonate buffer solution 0.2mL with biocides
Storage:	Refer to package labeling +4 °C to +30 °C (+39 °F to +86 °F) until expiry date
Stability:	Expiration date and lot number are printed on each cassette container label.
Shelf Life:	The stability of the cassette within the sealed pouch is **six months from date of manufacture.** **NOTE: Please take into account the minimum shelf life when placing your orders.**

6.6.7.4 Syringe Adapters (125 pcs)

Roche Reference Number - 03133559180

Use:	For use with Roche OPTI R cassettes when sampling from syringes
Contents:	Each package contains an insert sheet and one hundred twenty-five (125) adapters in a plastic bag.

6.6.7.5 Syringe Adapters (30 pcs)

Roche Reference Number - 03144267001

Use:	For use with Roche OPTI R cassettes when sampling from syringes
Contents:	Each package contains an insert sheet and thirty, (30) adapters in a convenient application tray.

6.6.7.6 Roche OPTI-check (Quality Control Material)

Roche Reference Number - 03113027180

Use:	For quality control measurement of pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb and SO_2 with the OPTI R Critical Care Analyzer.
Contents:	Each tri-level package contains 30 vials. 10 (1.7mL) each of level 1, 2 and 3. Package contains insert sheet with bar coded assay ranges for easy entry into the OPTI R Analyzer.
Composition:	Level 1: Respiratory acidosis as represented by pH and PCO_2 values, with low PO_2. Low values of Na^+, K^+, Cl^- and SO_2. High values of Ca^{++} and tHb. Vials identified by a red label. Level 2: Normal values with moderately decreased SO_2. Vials identified by a yellow label. Level 3: Respiratory alkalosis as represented by pH and PCO_2 values with high PO_2. High values of Na^+, K^+ and Cl^-. Low values of Ca^{++} and tHb with normal SO_2. Vials identified by a blue label.
Storage:	Refer to package labeling

NOTE: When entering assay ranges on the OPTI R Analyzer be sure to use the correct assay sheet identified by "FOR USE WITH THE OPTI R ANALYZER ONLY".

7 Competition Analysis

7.1 Overview

Competition to the Roche OPTI R Analyzer will consist of direct competition to the Hospital Point of Care market. However, Roche offers a truly portable multi-use analyzer for use in Hospital Point of Care Applications.

7.2 Analyzers for Decentralized Use

7.2.1 Overview (Competitors to the OPTI R Analyzer)

Feature	OPTI R	IL Gem Premier PLUS	IL Gem Premier 3000 *	OPTI CCA	Bayer – Chiron 865	i-STAT	Diametrics IRMA
Measured Parameter	pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb, SO_2, Baro	pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Hct	pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Hct	pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Cl^-, tHb, SO_2, Baro	pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, Lactate tHb, O2Hb, HHb, COHb, MetHb, Baro	pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct, BUN, Glucose	pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Hct, Baro
Sample Size Capillary Syringe	 125µL 125µL	 200µL	 135µL	 125µL 125µL	 Approx. 50µL Approx. 100µL	 65 - 130µL 65 – 130µL	 N/A 125 - 200µL
Sample Type	Whole blood Serum Plasma Aqueous Solutions	Whole blood	Whole blood	Whole blood Serum Plasma Dialysate Solutions Aqueous Solutions	Whole blood Serum Plasma Aqueous Buffers	Whole blood	Whole blood
Analysis Time	Approx. 60 seconds	Approx. 104 seconds	Approx. 104 seconds	Approx. 90 seconds	Approx. 60 seconds	Approx. 90 – 120 seconds	Approx. 90 seconds
Complete Measurement Cycle Time	Approx. 150 seconds	Not Specified	Not Specified	Approx. 150 seconds	Approx. 120 seconds	Approx. 90 – 120 seconds	Not Specified
Sample Application	Syringe Capillary	Syringe	Syringe	Syringe Capillary	Syringe Capillary	Syringe Capillary	Syringe Special Capillary
Sampling Technique	Aspiration	Injection	Injection	Aspiration	Aspiration	Injection	Injection
Dilution Ratio	without dilution	without dilution	without dilution	without dilution	without dilution	without dilution	without dilution

Feature	OPTI R	IL Gem Premier PLUS	IL Gem Premier 3000 *	OPTI CCA	Bayer – Chiron 865	i-STAT	Diametrics IRMA
Measurement Range							
pH	6.6 – 7.8	6.8 – 7.8	6.8 – 7.8	6.6 – 7.8	6.5 – 8.0	6.8 – 8.0	6.0 – 8.0
PCO2	10 – 200 mmHg	5 – 99 mmHg	5 – 115 mmHg	10 – 200 mmHg	5 – 250 mmHg	10 – 100 mmHg	4 – 200 mmHg
PO2	10 – 700 mmHg	0 – 760 mmHg	0 – 760 mmHg	10 – 700 mmHg	0 – 800 mmHg	5 – 800 mmHg	20 – 700 mmHg
Na+	100 – 180 mmol/L	100 – 200 mmol/L	100 – 200 mmol/L	100 – 180 mmol/L	70 – 200 mmol/L	100 – 180 mmol/L	80 – 200 mmol/L
K+	0.8 – 10 mmol/L	0.1 – 20 mmol/L	0.1 – 20 mmol/L	0.8 – 10 mmol/L	0.5 – 20.0 mmol/L	2 – 9 mmol/L	1.0 – 20 mmol/L
Ca++	0.2 – 3.0 mmol/L	0.1 – 5.0 mmol/L	0.1 – 5.0 mmol/L	0.2 – 3.0 mmol/L	0.25 – 5.0 mmol/L	65 – 140 mmol/L	0.2 – 5.0 mmol/L
Cl-	N/A	N/A	N/A	50 – 160 mmol/L	.6 – 55.4 mmol/L	1.1 – 25.0 mmol/L	N/A
Glu	N/A	N/A	N/A	N/A	10 – 998 mmol/L	20 – 450 mmol/L	N/A
Glu	N/A	N/A	N/A	N/A	N/A	.6 – 55.4 mmol/L	N/A
Urea	N/A	N/A	N/A	N/A	N/A	1 – 50 mmol/L	N/A
BUN	N/A	N/A	N/A	N/A	N/A	3 – 140 mmol/L	N/A
tHb	5 – 25 g/dL	N/A	N/A	5 – 25 g/dL	2 – 25 g/dL	N/A	N/A
SO2	60 – 100 %	N/A	N/A	60 – 100 %	0 – 100 %	N/A	N/A
Resolution of Display							
pH	0.001	0.01	0.01	0.001	0.001	0.001	0.01
PCO2	0.1 mmHg	1 mmHg	1 mmHg	0.1 mmHg	0.1 mmHg	0.1 mmHg	1 mmHg
PO2	0.1 mmHg	1 mmHg	1 mmHg	0.1 mmHg	0.1 mmHg	1 mmHg	1 mmHg
Na+	0.1 mmol/L	0.1 mmol/L	1 mmol/L	0.1 mmol/L	0.1 mmol/L	1 mmol/L	1 mmol/L
K+	0.01 mmol/L	0.01 mmol/L	0.1 mmol/L	0.01 mmol/L	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L
Ca++	0.01 mmol/L	0.01 mmol/L	0.01 mmol/L	0.01 mmol/L	0.01mmol/L	0.01 mmol/L	0.01 mmol/L
Cl-	N/A	N/A	N/A	0.1 mmol/L	0.1 mmol/L	0.1 mmol/L	N/A
Glu	N/A	N/A	N/A	N/A	0.1 mmol/L	mmol/L	N/A
Glu	N/A	N/A	N/A	N/A	N/A	mmol/L	N/A
Urea	N/A	N/A	N/A	N/A	N/A	mmol/L	N/A
BUN	N/A	N/A	N/A	N/A	N/A	mmol/L	N/A
tHb	0.1 g/dL	N/A	N/A	0.1 g/dL	0.1 g/dL	N/A	N/A
SO2	0.1 %	N/A	N/A	0.1 %	0.1 %	N/A	N/A
Type of Display	LCD, 2 Line	monochrome touchscreen	color touchscreen	LCD, 2 Line	monochrome backlit CRT	LCD	LCD touchscreen
Printout of all Values	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Calibration	Fully Automatic	Fully Automatic	Fully Automatic	Fully Automatic	Fully Automatic	Fully Automatic	Fully Automatic

Feature	OPTI R	IL Gem Premier PLUS	IL Gem Premier 3000 *	OPTI CCA	Bayer – Chiron 865	i-STAT	Diametrics IRMA
RS232 Interface	Standard, 9600 baud & IR, 9600 baud	2 Standard 1 Parallel	23 Standard 1 Parallel 1 Ethernet	Standard, 9600 baud & IR, 9600 baud	Standard Only	IR Transmission Only	Standard Only
Visible Sample Chamber	No	No		No	Yes	Yes	Yes
Self-Diagnostics	Yes	Yes	Yes	Yes	Yes	Yes	Not Specified
Data Management	Storage of > 150 patient samples with calibration data, and 3 levels of QC measurements for 1 month, calculation of mean, SD, CV%	Storage on 3.5" disk	Storage on 3.5" disk	Storage of > 150 patient samples with calibration data, and 3 levels of QC measurements for 1 month, calculation of mean, SD, CV%	Storage of 5000 patient samples and 100 QC data	50 patient data transmission to a central data station via IR	Storage of 200 patient samples and QC tests for 32 days
Power Supply	Rechargeable NICAD battery pack, or AC power adapter supplied, with 90-250VAC, 50/60Hz	Switching Power Supply, 60 minute power interrupt allows transport. AC required for operation 90-264VAC, 50/60Hz	Switching Power Supply, 60 minute power interrupt allows transport. AC required for operation 90-264VAC, 50/60Hz	Rechargeable NICAD battery pack, or AC power adapter supplied, with 90-250VAC, 50/60Hz	100-240VAC Automatic 50/60Hz	2x9 lithium batteries non-rechargeable	Batter or AC power, adapter supplied with 115-230VAC, 50/60Hz
Dimensions height width depth weight	 4.87 in (124mm) 14.25 in (362mm) 9.75 in (248mm) 10 lbs (approx 4.5kg)	 16.5 in (41.9cm) 12.0 in (30.5cm) 10.5 in (26.7cm) 29.5 lbs (approx 13.4kg)	 17.0 in (43.2 cm) 12.0 in (30.5cm) 12.0 in (30.7cm) 29.5 lbs (approx 13.4kg)	 4.87 in (124mm) 14.25 in (362mm) 9.75 in (248mm) 10 lbs (approx 4.5kg)	 18.8 in (460mm) 27.7 in (700mm) 19.8 in (500mm) approx 82 lbs (37 kg)	 8.3 in (210mm) 2.5 in (64mm) 1.9 in (48mm) aprox 1.2 lbs (0.53kg)	 5.0 in (127mm) 11.5 in (292mm) 9.5 in (241mm) approx 3.5 lbs (1.6kg)
Sensors Type							
pH	Fluorescence Multi-Use Cartridge	Potentiometric	Potentiometric	Fluorescence Single-Use Cartridge	pH sensitive glass electrode with calomel reference electrode	thin-film electrodes micro-fabricated onto silicon chip	thick-film micro-electrode single-use cartridge

Feature	OPTI R	IL Gem Premier PLUS	IL Gem Premier 3000 *	OPTI CCA	Bayer – Chiron 865	i-STAT	Diametrics IRMA
PCO2	Fluorescence Multi-Use Cartridge	Potentiometric	Potentiometric	Fluorescence Single-Use Cartridge	modified pH sensitive glass electrode covered with a CO2 permeable membrane	thin-film electrodes micro-fabricated onto silicon chip	thick-film micro-electrode single-use cartridge
PO2	Fluorescence Multi-Use Cartridge	Amperometric	Amperometric	Fluorescence Single-Use Cartridge	PO2 sensitive glass electrode with platinum cathode and silver anode	thin-film electrodes micro-fabricated onto silicon chip	thick-film micro-electrode single-use cartridge
Na+	Fluorescence Multi-Use Cartridge	Potentiometric	Potentiometric	Fluorescence Single-Use Cartridge	Sodium sensitive glass, flow-through electrode	thin-film electrodes micro-fabricated onto silicon chip	thick-film micro-electrode single-use cartridge
K+	Fluorescence Multi-Use Cartridge	Potentiometric	Potentiometric	Fluorescence Single-Use Cartridge	K+ ion selective, liquid membrane flow-through electrode	thin-film electrodes micro-fabricated onto silicon chip	thick-film micro-electrode single-use cartridge
Ca++	Fluorescence Multi-Use Cartridge	Potentiometric	Potentiometric	Fluorescence Single-Use Cartridge	Ca++ ion selective, liquid membrane flow-through electrode	thin-film electrodes micro-fabricated onto silicon chip	thick-film micro-electrode single-use cartridge
Cl-	N/A	N/A	N/A	Fluorescence Single-Use Cartridge	Cl- ion selective, liquid membrane flow-through	thin-film electrodes micro-fabricated onto silicon chip	N/A
Glu	N/A	N/A	N/A	N/A	Enzyme / Amperometric thick-film technology	thin-film electrodes micro-fabricated onto silicon chip	N/A
BUN (urea)	N/A	N/A	N/A	N/A	N/A	thin-film electrodes micro-fabricated onto silicon chip	N/A

Feature	OPTI R	IL Gem Premier PLUS	IL Gem Premier 3000 *	OPTI CCA	Bayer – Chiron 865	i-STAT	Diametrics IRMA
tHb	Light Scattering reflectance, Multi-Use Cartridge	N/A	N/A	Light Scattering reflectance, Multi-Use Cartridge	Multi-Wavelength Co-oximeter	N/A	N/A
SO2	Light Scattering reflectance, Multi-Use Cartridge	N/A	N/A	Light Scattering reflectance, Single-Use Cartridge	Multi-Wavelength Co-oximeter	N/A	N/A
Multi-Use Pak Capacity	90 – 120	150 or 300	150 or 300	N/A	N/A	N/A	N/A
Multi-Use Pak In-use Expiration	4 weeks	14 days	21 days	N/A	N/A	N/A	N/A
Multi-Use Cartridge Capacity	25 Patient Sample + 35 QC	N/A	N/A	N/A	N/A	N/A	N/A
Multi-Use Cartridge Expiration	5 Days	N/A	N/A	N/A	N/A	N/A	N/A

* Gem Premier 3000 replaces the Gem Premier PLUS

7.2.2 Instrumentation Laboratories (http://www.ilww.com)

Corporate information collected via the internet and/or other Instrumentation Laboratories sources and is subject to change.

GEM Premier

GEM PCL

Strengths

- Market Leader in the OR
- Menu- ITC POC Coag with ACT (Activated Clotting Time)
- Low cost of Multiple Cassette Pack if all tests are used

Weaknesses

- Capital Outlay – High analyzer cost
- Large Size
- Difficult to Accommodate Varied Testing Volumes
- Test Packs available in 150 or 300 tests-Many Perfusionists will throw out remaining pack at end of day which results in a lot of wastage
- One Hour Warm Up Time
- Changing a Cartridge is Time Consuming
- It takes a minimum of 1 hour minutes to perform a cartridge change (*PLUS*), Not stated for the 3000
- Limited Connectivity (*PLUS*)
- Serial Cable Only (*PLUS*)

Roche Advantages to Highlight

- Small Size and Battery Option of the OPTI R Analyzer
- More Flexibility and Portability options
- Bar Code Scanning Capability for entry of Accession number, Operator ID, Patient ID, QC and Cassette Calibration/Lot Information
- Significant reduction in the potential for operator entry
- Emphasize Minimal Maintenance Requirements of the OPTI R Analyzer

GEM Position/Roche Response

POSITION

Benchtop technology is more accurate and reliable than optical technology.

Roche RESPONSE

Six point calibration done at the factory along with a calibration prior to each individual measurement or at thirty minute intervals (whichever comes first) ensures reliability. Also correlation data to bench top technology is excellent.

7.2.3 Bayer Diagnostics / Chiron (http://www.Bayerdiag.com)

Corporate information collected via the internet and/or other Bayer Diagnostic Corporation sources and is subject to change.

Vision

Bayer is committed to changing the world with great care. Our vision is to be a leader in the markets we serve and to be a major contributor to our worldwide parent company. We will achieve our Vision through a diversified, highly motivated work force, by satisfying and retaining loyalties of our external and internal customers; with an organization that fosters teamwork and is unencumbered by bureaucracy; by being environmentally responsible and by being good corporate citizens in the communities in which we work and live.

Company Profile

About Bayer Diagnostics

Bayer Diagnostics is one of the largest and fastest growing medical diagnostics businesses in the world. Eight thousand employees touch the lives of five million patients daily in more than 100 countries worldwide. Bayer designs, manufactures and markets clinical diagnostics systems for the major industry markets of Self-Testing, Near Patient Testing (Hospital Point of Care and Critical Care), Laboratory Testing, and Nucleic Acid Diagnostics. The company has more than 50 branch offices, seven major manufacturing plants, and an extensive global distribution network. Bayer Diagnostics is a part of the worldwide Bayer Group, a $29 billion international life sciences, polymers and specialty chemicals group based in Leverkusen, Germany. Bayer Corporation is the name of the Bayer Group's U.S. operations.

Critical Care Diagnostics

Critical Care diagnostic testing includes routine and time-sensitive testing for critically ill patients in a variety of areas including pH/blood gases, electrolytes, metabolites, CO-oximetry and coagulation. Physicians are requesting a wider array of blood tests to obtain the information they need

to understand a patient's situation and make decisions about diagnosis, monitoring and treatment quickly. Accordingly, demand is rising for a cost-effective and reliable instrument that can be managed by the lab and also operated in close proximity to the patient. Integrated and networked by Rapidlink, Bayer is providing that technology, delivering results in seconds to hospital laboratories, critical and intensive care units, operating rooms, emergency rooms and the patient's bedside.

Rapidpoint™ 400 (Not Released)

The Rapidpoint™ 400 is a sophisticated whole blood analysis system that is designed specifically for point of care testing while also satisfying the stringent requirements of the central laboratory. A single, multiple-use measurement cartridge contains all of the components of a traditional laboratory analyzer. This long-lasting cartridge includes the sampling unit, all of the sensors, and all calibrating reagents. No gas tanks are required. A wash/waste cartridge contains the wash solution and also serves as the collection device for all of the waste, providing a completely closed, bio-safe system. The Rapidpoint 400 System fully automates the entire testing process to provide standardized, laboratory-quality testing at every test site. It delivers whole blood results in just 60 seconds for one test or a complete panel, with the most complete point of care menu available, pH, blood gas, electrolytes, glucose and hematocrit, all with the capability to be monitored remotely by the central laboratory. Rapidpoint 400 uses a zero maintenance, cost-effective multi-use cartridge and auto sampling provides consistent results. A color touch screen with icons and video guidance ensures ease of use.

Rapidlab™ 800

The Rapidlab™ 800 System is a fully automated, upgradable platform that covers the key critical care whole blood parameters in addition to comprehensive on-board information allows the basic blood gas model to be quickly and easily upgraded to include electrolytes, metabolites and CO-oximetry in a single unit. This versatility addresses changing clinical demands by eliminating the need for the laboratory to buy an additional system when only additional testing parameters are needed. The Rapidlab™ 800 Smart Sampler™ device, automatically measure a single sample and makes the system easy to use, accurate and safe. Maintenance requirements are minimal due to the simple hydraulic design and long life Ready Sensors.

7.2.4 i-STAT (http://www.i-STAT.com)

Corporate information collected via the internet and/or other i-STAT Corporation sources and is subject to change.

Mission

i-STAT Corporation's mission is to improve the quality and reduce the cost of health care by providing products that improve the process of patient care.

Company Profile

Technology

A recognized leader in point-of-care blood analysis products. i-STAT's proprietary core technology provides a revolutionary method of blood analysis. The Company has developed the world's only fully-automated, pocket-size analyzer which performs a complete panel of the most commonly ordered blood tests in a simple procedure at the point of patient care. i-STAT has combined established principles of electrochemistry with micro-fabrication process technology from the semiconductor industry to create this revolutionary breakthrough.

Products

The Company introduced its first product, the i-STAT® System, into the US acute care hospital market in mid-1992. Designed for use at the point of patient care, the system consists of two components: 1) a handheld microprocessor-based analyzer and 2) disposable test cartridges which contain an array of biosensors microfabricated onto silicon chips. A comprehensive data management system ensures all test results are seamlessly integrated into any laboratory or clinical information system.

Overview

The i-STAT® System incorporates everything needed to perform blood analysis at the patient bedside. Single-use, disposable test cartridges and a micro-processor controlled, handheld analyzer allow true mobility to all areas of the hospital where the immediacy of test results is clinically valuable. Portable printers and infrared communication interfaces allow all patient information obtained at the bedside to be printed on demand and uploaded to the hospitals' centralized information systems for record keeping and billing.

In late 1994 i-STAT Corporation expanded its technology in portable blood analysis by developing a blood gas test panel (pH, PCO2 & PO2) to complement its existing test menu of electrolytes and blood chemistries. An enhanced version of i-STAT's Portable Clinical Analyzer was introduced to provide thermal control for those tests that require measurement at 37°C. Entry of demographic information was expanded beyond patient and user identification numbers to include patient temperature, sample type (arterial,

venous, capillary), FIO2 and three user-definable fields for data such as ventilator settings.

The addition of blood gas testing to the i-STAT System enables members of the medical staff to quickly assess metabolic conditions, monitor mechanical ventilation, oxygen therapy or medications, and immediately react to complications without leaving the patient's side. A broad range of laboratory tests are available in a variety of panel configurations that include: pH, PCO2 PO2, activated clotting time (ACT), glucose, lactate, creatinine, sodium, potassium, chloride, ionized calcium, urea nitrogen (BUN), hematocrit and various calculated parameters. The testing process is contained in a single-use disposable cartridge that self-calibrates miniaturized sensors upon use.

The unique technology also eliminates maintenance and reduces the complexity of performing quality control. Just 2-3 drops of fresh whole blood is all that is required, and the portable, battery-powered analyzer displays quantitative test results in just over 2 minutes. The i-STAT System is currently in use in more than 2000 hospitals in the United States.

Strategy

The Company's strategy is to become the standard of care for stat blood analysis at the patient's side. Its current product offering directly addresses a $3.0 billion segment of the worldwide US $19 billion in vitro diagnostic market. Continued technology/product development and penetration of additional markets, both international and domestic, will create continued growth and expansion of i-STAT. In the US, the i-STAT System is currently used in over 2000 hospitals to perform critical blood analyses. The Company's larger US customers have implemented the i-STAT System throughout all of their critical care departments and are using it as their principal means of performing stat tests.

Distribution & Strategic Alliances

In September 1998, i-STAT Corporation and Abbott Laboratories entered into a strategic alliance that includes a worldwide distribution agreement for i-STAT's products in the professionally-attended human healthcare market. The alliance with Abbott also includes collaboration in the development of new products as well as an equity ownership position in the Company. Except in Japan, the i-STAT System is sold exclusively by Abbott. In Japan, the i-STAT System is marketed on a nonexclusive basis by both FUSO Pharmaceutical Industries and Dainabot Co. Ltd., Abbott's Japanese affiliate.

The Company has a license agreement with Agilent Technologies, a Hewlett-Packard subsidiary, which provides for the integration of i-STAT technology into patient monitors. In 1997, Hewlett-Packard launched the HP Blood Analysis Module which uses i-STAT cartridges to perform blood analysis with HP's market-leading Omnicare Component Monitoring System. HP markets the Blood Analysis Module worldwide. Heska Corporation is the exclusive worldwide distributor of the i-STAT System to the veterinary market.

Organization & Facilities

i-STAT Corporation currently operates two facilities and employs approximately 600 people. A diverse Company staff includes manufacturing personnel, process engineers, research and development scientists and engineers (mechanical, electrical, and chemical), a software engineering and development group, a technical/clinical services organization, a quality systems group, a marketing group, a field-sales consulting and implementation staff, and other corporate support functions such as finance and accounting, information systems and human resources. The corporate offices are located in East Windsor, NJ, and accommodates the finance group, clinical and technical services, customer support, distribution, and research and development laboratories, and other corporate functions. The corporate facility also includes an instrument (the handheld analyzer) engineering and assembly unit. A technology and manufacturing facility is located in Kanata, Ontario, Canada, (a suburb of Ottawa) and includes research and development laboratories, a wafer fab, and three cartridge assembly production lines.

Product Information (Cassette Types Available)

Cassette Type	* EC 8 +	* EG 7 + 37°	EC + 6	EG6 + 37°	+ 6	EC 4 +	G 3 + 37°	E 3 +	G
Measured parameters	Sodium Potassium Chloride Urea Nitrogen Glucose pH PCO2 Hematocrit	Sodium Potassium Ionized Calcium pH PCO2 PO2 Hematocrit	Sodium Potassium Glucose Ionized Calcium pH Hematocrit	Sodium Potassium pH PCO2 PO2 Hematocrit	Sodium Potassium Chloride Urea Nitrogen Glucose Hematocrit	Sodium Potassium Glucose Hematocrit	pH PCO2 PO2	Sodium Potassium Hematocrit	Glucose
Calculated Paremeters	Bicarbonate Total Carbon Dioxide Base Excess Anion Gap Hemoglobin	Bicarbonate Total Carbon Dioxide Base Excess O2 Saturation Hemoglobin	Hemoglobin	Bicarbonate Total Carbon Dioxide Base Excess O2 Saturation Hemoglobin	Hemoglobin	Hemoglobin	Bicarbonate Total Carbon Dioxide Base Excess O2 Saturation	Hemoglobin	

* Most popular cassette configuration

Strengths:

- Market Acceptance-POCT pioneer
- Menu-Wide menu available
- Size-Many like the small, "cell phone" look
- Abbott Alliance-This gives new clout and increased coverage
- On Board QC-Electronic QC integrated into system; No need to run separate electronic QC

Weaknesses:

- **Refrigeration of Cassettes Required** - Cassettes good for 6 months in refrigerator; Two weeks out of refrigerator at room temp
- **Four Hour Equilibration Time** - Cassettes require this time before they can be used when brought out of the refrigerator or fifteen (15) minutes for individual blood gas cassettes
- **Immediate Use of Cassette Required** - Once pouch is opened cassette must be used immediately
- **Limited On Board Data Management** - Stores only 50 patients and two weeks of QC
- **No QC Lock Out** - Operators risk running samples on analyzers that have failed QC
- **Introduction of Sample** - Sample must be filled to fill mark upon introduction; can result in under or overfilling of cassette; Increases training time required
- **Calculated Thb and 02 Saturation** - Directly measures HCT via conductivity which can be problematic in OR settings
- **Temperature Sensitivity in OR Environment** - Unable to maintain ambient temperature in the "cool" OR suites; Begun providing blanket like "wraps" for use in this area
- **User ID Feature Offers Minimal Security** - Any operator id will work-as long as it is entered twice
- **Not Menu Driven** - Operator must memorize functions that keys represent including 02 therapy areas
- **No On Board Printer** - Printer is separate and must be aligned correctly to transfer data by IR
- **Sample Testing Process** - Potential for loss of patient sample due to the way sample is introduced; (Insert blood into cartridge then place cartridge in analyzer for calibration)
- **Cannot Handle Iced Samples**

Roche Advantages to Highlight:

- Room Temperature Storage of Cassette
  - Eliminates logistics nightmares of re-labeling expiration dates, etc.
- Automatic Aspiration of Sample
  - Minimizes training time, overall easier to use
- Out of Pouch Stability of 60 Minutes
  - If operator is called away after cassette is opened, the cassette is still good
- Flexible Connectivity Options

- Calibration of Cassette is performed PRIOR to the aspiration of the patient sample – Calibration of the cassette is after previous patient/QC sample or every thirty minutes (whichever comes first) and is valid for the next patient/QC sample
  - i-Stat introduces the blood sample and then calibrates the cartridge; if cartridge fails calibration, then sample is lost-especially important in NICU's where blood is scarce
- Extensive Patient/Demographic/02 Therapy Entry
  - User can enter FiO2 information only on O2 Therapy Screen
- Bar Code Scanner Capability
  - Number-one source of error with i-Stat is incorrect patient id entry
- Direct Measurement of tHb
  - HCT via conductivity is a major source of problems in the OR

i-Stat Position/Roche Response

POSITION

Other instruments are too large to be considered true Point of Care.

Roche RESPONSE

The OPTI R Critical Care Analyzer has the flexibility of being utilized in the battery mode for portable use as well as the AC mode for more stationary use. No need to purchase additional lithium batteries. No risk of loss due to small size.

POSITION

It only takes a few drops of blood to perform a patient test.

Roche RESPONSE

This is true for electrolyte analysis, however, for blood gas testing, you must have a minimum of 130µl of blood. Also, after implementation, i-STAT recommends obtaining "extra" blood for pre-analytical "drop" onto a gauze pad for optimum results.

POSITION

The i-STAT System has no maintenance requirements.

Roche RESPONSE

The OPTI R's maintenance requirements are minimal. Demonstrate that our maintenance can easily be performed by both nursing and OR personnel.

POSITION

The i-STAT System interfaces to any HIS/LIS via an "off the shelf" product.

Roche RESPONSE

The i-STAT Central Data Station can be interfaced to all HIS/LIS, however, all interfacing requires the presence of i-STAT hardware. Interfacing to other Point-of-Care instruments cannot be easily performed, and in many instances, is impossible. Emphasize the flexibility and capabilities of the OPTI R Critical Care Analyzer.

7.2.5 Diametrics (Agilent/HP) (http://Diametrics.com)

Corporate information collected via the internet and/or other Diametrics Corporation sources and is subject to change.

Mission

It is the mission of Diametrics Medical Inc. to transform the process of critical care. Diametrics is accomplishing this through the dynamic integration of two world class technologies with the need of health care professionals to provide high quality care to critically ill adult, pediatric and neonatal patients.

Diametrics continually strives to raise the standard of care by:

Expanding product applications of both the continuous monitoring and point of care testing technologies forging strategic manufacturing and distributor partnerships enhancing company performance

It is through this mission of dynamic integration that Diametrics Medical will achieve its strategic intent to be:

The World Leader in Critical Care Blood and Tissue Analysis Systems.

Electrochemical Technology – Point of Care Testing Products

The cornerstone of our electrochemical technology is the IRMA® SL Blood Analysis System. This point of care testing system is a small, portable, integrated workstation that allows clinicians to test at the bedside, and immediately receive results for blood gases, electrolytes, hematocrit and glucose. Diametrics will continue to expand the testing menu of the IRMA System, as well as, the flexibility of the system and its adaptability in many

clinical situations.Agilent Technologies' IRMA Blood Analysis System delivers laboratory-quality blood test results where they're needed most -- at the point of care. IRMA is intended for use in adult, pediatric, and neonatal intensive care; surgery and post-anesthesia; and emergency applications. Point of care blood testing is designed to reduce turnaround time of test results, streamline processes, increase staff efficiency, improve outcomes, and reduce overall operating costs.

Product Information (Cassette Types Available)

Cassette Type	Combo (CC)	Blood Gasses	H3	* H4
Measured Parameters	pH, PCO2, PO2, Na+, K+, Ca++, Hct	pH, PCO2, PO2	Na+, K+, Ca++, Hct	Na+, K+, Cl-, BUN, Hct
Calculated Paremeters	HCO3, TCO2, BEecf, BEbid, SO2, Hb, iCa(n)	HCO3, TCO2, BEecf, BEbid, SO2	Hb	Hb

- H4 Cartridge type not yet released

Strengths

- Alliance with Hewlett-Packard
- Glucose strip testing directly incorporated into IRMA
- Lightweight (5.5 lbs.)
- AVOX Cooximeter
- Measures tHb, 02 Sat., MetHb, and COHb
- Data Storage Capabilities
- 200 Patients and 300 QC Results

Weaknesses

- Injection Technique
- Potential for blood splatter
- Operator must displace gel which can result in “gel” readings vs. blood readings
- More training/inservicing time required
- Manual Entry of Cartridge Calibration –
  - Operator must enter cal code, lot information, and patient id which can result in operator errors; These must be corrected by POCT coordinator at the IDMS (computer) level
- Cartridge needs to equilibrate to hospital temperature for 72 hours prior to use
- Difficult to use in the OR setting
- Cartridges must be used in the operating range of 59°-86°F ; If cartridges are stored outside the OR suite, then it takes 72 hours to equilibrate to the OR temperature
- Cartridge Shelf Life 5 Months
- Open Pouch Stability 10 Minutes
- Not Compatible with Regular Capillary tubes
  - Must purchase proprietary capillary device at approx. $1.00 each
- Interfaces to LIS/HIS are Minimal

- Currently interface to Cerner and Sunquest
  - Having major difficulties interfacing to Meditech

Roche Advantages to Highlight

Automatic Aspiration of Sample

- Eliminates any special techniques required for sample introduction
- Minimizes training requirements
- No chance of blood splatter
- Uses standard capillary tubes-no additional expense

Bar Code Capability

- Calibration Code entered via bar code on cassette
- Bar Code Reader available for operator and patient data entry

Ability to Edit/Delete/Review Records at Instrument Level

- Irma must be done at Data Management Level

Extensive Shelf Life of Cassettes

- 6 Months

Open Pouch Stability of One hour

- 10 minutes on Diametrics Irma

IRMA Position/Roche Response

POSITION

Roche OPTI takes too long to calibrate

Roche RESPONSE

Roche has a comprehensive calibration process to ensure reliability. Although the calibration time may be seconds longer, we make up for it in shelf life, bar code calibration data, ease of sampling, etc.

POSITION

Roche is too heavy to be POC. It can only be utilized as Near Patient.

Roche RESPONSE

The majority of hospitals utilizing IRMA Analyzers are using them as Near Patient devices. It is not financially feasible for a hospital to purchase an IRMA Analyzer for every bedside. The OPTI R is still portable.

POSITION

The OPTI R requires a lot of maintenance.

Roche RESPONSE:

No instrument is totally maintenance free. The maintenance requirements of the OPTI R are minimal.

7.2.6 Radiometer (http://www.Radiometer.com)

Corporate information collected via the internet and/or other Radiometer Corporation sources and is subject to change.

More than 40 years' experience in the blood gas business makes RADIOMETER™ the pioneer in this field. The Denmark-based company develops, manufactures, markets and services state-of-the-art critical care and monitoring equipment. RADIOMETER offers state-of-the-art blood gas analyzers, including analyzers for electrolytes, oximetry and metabolites – supported by superior training and service.

RADIOMETER, in cooperation with the clinical chemistry pioneer Prof. Poul Astrup, M.D., introduced the world's first acid-base analyzers in 1954. Ever since, RADIOMETER has continued to innovate.

RADIOMETER blood gas analyzers combine durability, ease of use, and minimal maintenance with the highest level of measuring accuracy. A full range of analyzers covers everything from basic needs to the most comprehensive parameter combination.

RADIOMETER also offers a full program of support services – including individually tailored training courses for doctors, nurses and laboratory staff. This ensures optimal use of the equipment.

RADIOMETER has a world wide sales and service support network ready to help in more than 100 countries around the globe.

Radiometer ABL70

The ABL70 analyzer has been designed to meet special needs for near patient applications such as intensive care, emergency, operating rooms and cardiovascular surgery. The ABL70 combines the cost savings and accuracy

known from benchtop analyzers with the speed and convenience of a bedside device.

Broad Array of Parameters

The ABL70 provides a broad and flexible menu of pH, blood gases, electrolytes, and hematocrit. The panel of 7 parameters is measured in less than 60 seconds.

Always Ready to Measure

Compared to single-use cartridge devices, there is no cartridge preparation, calibration or temperature stabilization prior to the measurement, because the ABL is always ready to measure.

Shortest Start-up Time

The ABL70 has the shortest start-up time of any multiple test analyzer. When installing a new sensor cassette, the analyzer is ready for testing in about 7 minutes.

Virtually Maintenance Free

There are just two consumables: a multiple-test sensor cassette and a calibration pack which contains all solutions and a waste reservoir. Both are easily and quickly installed.

Intuitive Touch Screen Operation

The combination of the color touch screen and customizable menus makes the user interface intuitive and easy to use. Everyone can use the ABL70 with minimal instruction. No special user skills or training are needed.

Portable with Battery Operation

Weighing less than 15 pounds (6 kg) and smaller than any benchtop analyzer, the ABL70 can easily be brought to any Near Patient Testing setting with true flexibility of use. The automatic battery operation enables patient samples to be run on the analyzer, even during power disruptions or extended transport.

Easy Data Transfer and Storage

The ABL70 has an integrated bar code reader for easy and secure transfer of patient ID, user ID, and accession numbers. Patient data can be saved in the system's memory, on a 3.5" diskette or sent via the serial port connector to the hospital's information system.

Enhanced Manager Control

The ABL70 can be set up to lock out patient testing if QC fails or is not completed, and password protection is also an option to prevent unauthorized use.

Strengths

- Fast
  - Blood Analysis Time is 60 Seconds which is comparable with the OPTI R

Weaknesses

- Aspiration Probe needs to be cleaned after every sample
  - Time consuming and potential bio-hazardous exposure
- Measures HCT via Conductivity
  - Problems with plasma expanders in OR leading to falsely decreased levels
  - Many hospitals have said they have never transfused as many patients
- Blood Clots are a problem
  - No clot catchers

Roche Advantages to Highlight

- OPTI R is more portable
- OPTI R does not require a seven (7) minute “Warm Up” time
- Directly Measured tHb

Radiometer ABL77

The press release dated Copenhagen, October 26, 2000 shown below is provided as information on the new ABL77 Analyzer:

RADIOMETER Launches the World's Fastest Portable Blood Gas Analyzer

Copenhagen, Denmark, October 26, 2000

The following is an English version of the statement from Radiometer A/S to the Copenhagen Stock Exchange labeled "Meddelelse nr. 11/2000 " dated October 26, 2000. The statement is made to comply with Danish laws and regulations and is written in Danish. We have done our best to provide a fair and honest translation for our many non-Danish stakeholders - investors, employees, customers etc. - to provide the same factual information, but it should be emphasized that it is the Danish version for which Radiometer is legally responsible.

Today Radiometer has released the new blood gas instrument ABL™77 for sales.

The ABL77 is manufactured by Radiometer's subsidiary SenDx Medical, Inc. in Carlsbad California. The instrument is a further development of the

ABL70, which SenDx had developed prior to Radiometer's acquisition of the company in 1998.

The ABL77 has significantly improved software and measures on half the blood sample. Through the cooperation between SenDx Medical, Inc. and Radiometer Medical A/S the instrument has been made more user friendly and reliable.

With the ABL77 Radiometer offers the hospitals a quick and reliable blood gas instrument, which is portable and designed for use near the patient everywhere in the hospital. Such instruments are called Point-of-Care instruments.

The attached press release will today be forwarded to the press.

Copenhagen, October 26, 2000
RADIOMETER A/S

Johan Schrøder
President, CEO

Contact: Johan Schrøder, Tel.: +45 3827 3371

Press Release

RADIOMETER Launches the World's Fastest Portable Blood Gas Analyzer

Radiometer's product company SenDx Medical, Inc. in California has today released a new blood gas analyzer, specially developed for use in patient wards. The ABL™77 makes it easy for the nursing staff to measure important acute parameters in blood samples from critically ill patients.

The new ABL77 blood gas analyzer provides accurate results in approx. one minute, making the portable analyzer the world's fastest of its kind. Compared to most other portable blood gas analyzers in the market, the ABL77 is always ready for measuring and is virtually maintenance-free. There are no preparations of e.g. measuring cassettes before a blood gas measurement can be initiated. This means that an ABL77 is always ready for measuring so that the hospital staff saves time, and at the same time the risk of pre-analytical errors is minimized.

Small portable analyzers like the ABL77 are particularly in demand in the Point-of-Care segment, which is the fastest growing segment in the blood gas market. The Point-of-Care segment consists primarily of the hospital's patient wards where it is desirable to measure blood gases and other parameters close to the patients. Thus the doctors will have the information they need in the treatment of critically ill patient more quickly. Exactly because prompt measuring results are so important, the fast ABL77 analyzer will have a considerable competitive advantage in this segment.

An Important Milestone after the Acquisition of SenDx Medical Inc. The ABL77 is a further development of the analyzer generation, which

Radiometer took over when acquiring SenDx in 1998. “The introduction of the ABL77 is an important milestone for Radiometer and SenDx Medical Inc. because the analyzer is a result of the cooperation between the two organizations”, says Johan Schrøder, President & CEO of Radiometer A/S. “The new product includes a.o. Sensors and substrates that are the result of a joint development effort between Copenhagen and SenDx. In that way we have really managed to utilize the synergistic effects of bringing the two companies together."

The ABL77 is based on a thick-film sensor technology, and it measures pH, blood gases, three electrolytes and the hematocrit values on just 85 microliter blood. This is less than half the amount of blood used by the previous generation, and it makes the ABL77 well suited for neonatal and pediatric departments. The sensor cassette can be stored at room temperature and is sold in several configurations with different parameters and test volumes.

The ABL77 is operated via a large color screen, and the use of large icons makes the software very intuitive, even for the less experienced user. The operating system is Windows CE, and the software can very easily be configured according to the customer's needs. In addition, the ABL77 can easily be connected to the hospital's information systems.

With the introduction of the ABL77 Radiometer has further strengthened its product line which thus continues to be the most up-to-date and competitive total solution in the blood gas measurement market.

8 Evaluation Results

8.1 Field Test Results

8.1.1 Objective

The objective of these studies was to validate the performance of the Roche OPTI R Analyzer during normal operation, operated by minimally trained personnel.

8.1.2 Field Test Sites

These field test sites include both correlation to predicate devices and 20-day precision studies.

Six (6) field test sites were utilized in this study – three (3) U.S. and three (3) international reporting a combined number of patient samples of 1,346.

8.1.3 Overview of Study Protocol

According to the study design for the performance study four (4) lots of Roche OPTI R sensor cassettes and three (3) lots of Roche OPTI R SnapPak's (reagent) were utilized at the field test sites. Number of test units utilized for this study was nine (9).

8.1.4 Sample Range

Sample measured over this study fell within the following ranges per parameter.

Parameter	Low	High	Units
pH	6.890	7.600	pH
PCO_2	21.0	136.2	mmHg
PO_2	27.1	527.0	mmHg
Na+	99.1	171.0	mM
K+	1.8	9.4	mM
Ca++	0.5	2.5	mM
tHb	5.8	18.1	G/dL
SO_2	61.4	100.0	%

8.1.5 Conclusion

The Roche OPTI R performance as evaluated over all field trial sites performed within the specified acceptable limits for the analyzer.

This data also shows similarities to the currently available Roche OPTI critical Care Analyzer when operating with equivalent E-Ca Type single use cassettes.

This data was also reviewed as part of the Roche OPTI R peer review meeting held on September 19 and 20, 2000

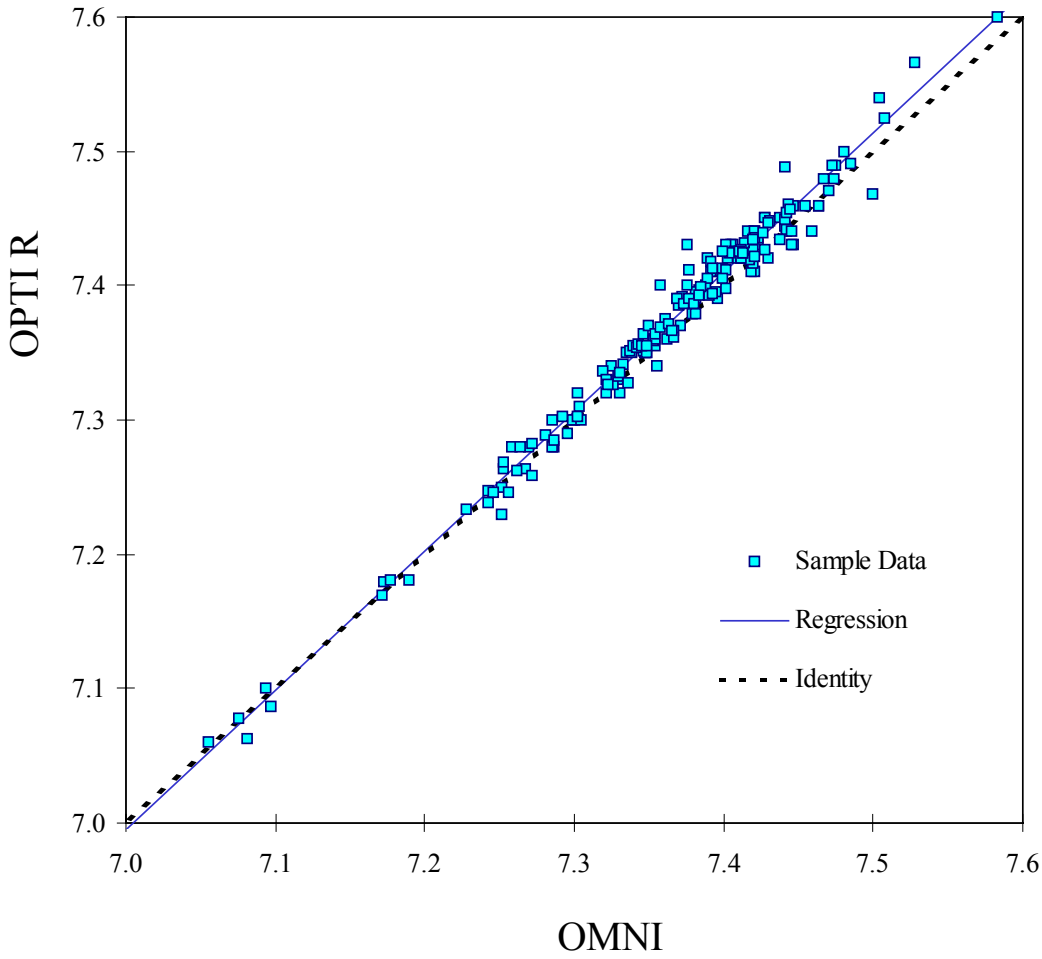
The following data attained at one of the field trial sites is presented as a comparison against the current Roche OMNI Analyzer.

NOTE: Data shown for iCa^{++} differs from the predicate device due to N.I.S.T. Standardization. The Roche OPTI R has been developed to the proposed N.I.S.T. standard (NCCLS Document C39-A, *A Designated Comparison Method for the Measurement of Ionized Calcium in Serum*, approved standard.

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. OMNI
pH



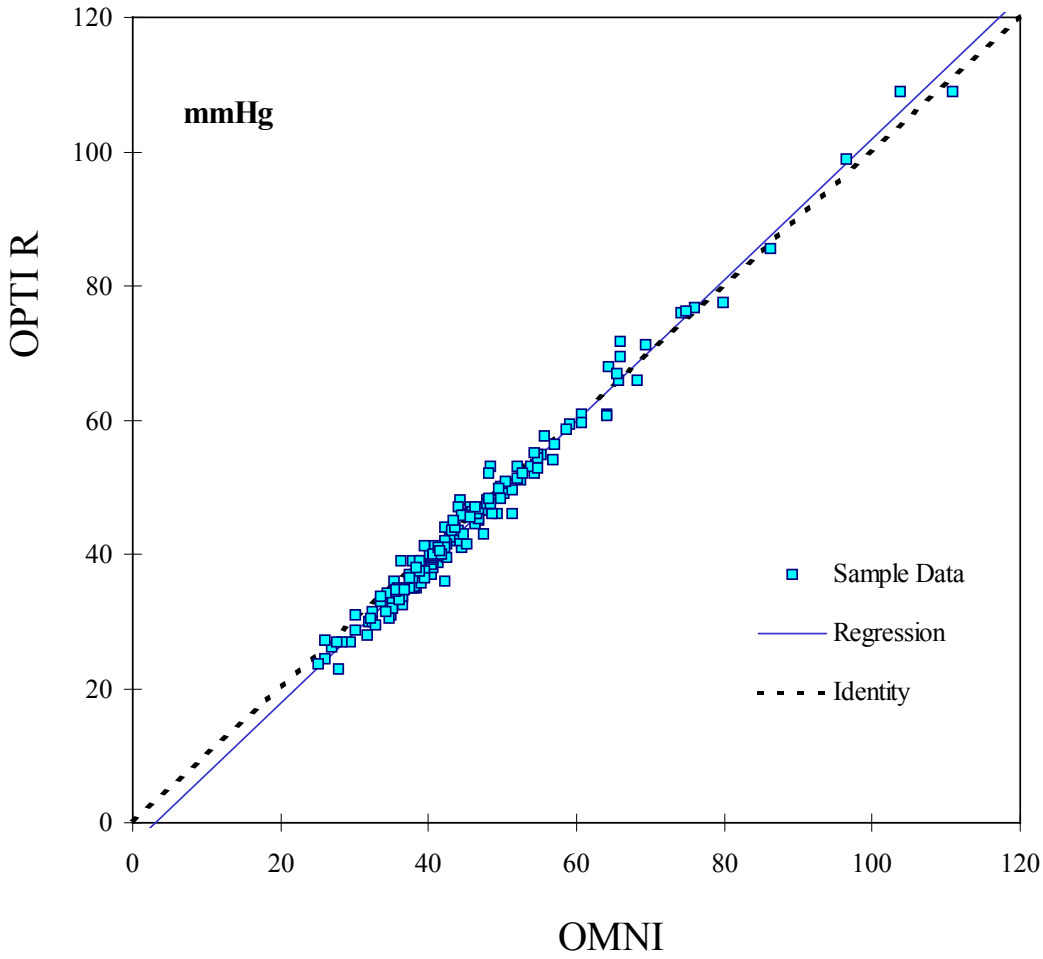
Correlation

number of pairs (n):	178
slope (m):	1.03717
y-intercept (b):	-0.26539
y-intercept (normalized):	0.0097
regression coefficient (r^2):	0.98167
correlation coefficient (r):	0.99079
std error of y estimate:	0.0121
average difference:	0.0083
SD of differences:	0.0125
P(T<=t) two-tail:	0.37

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. OMNI
PCO2



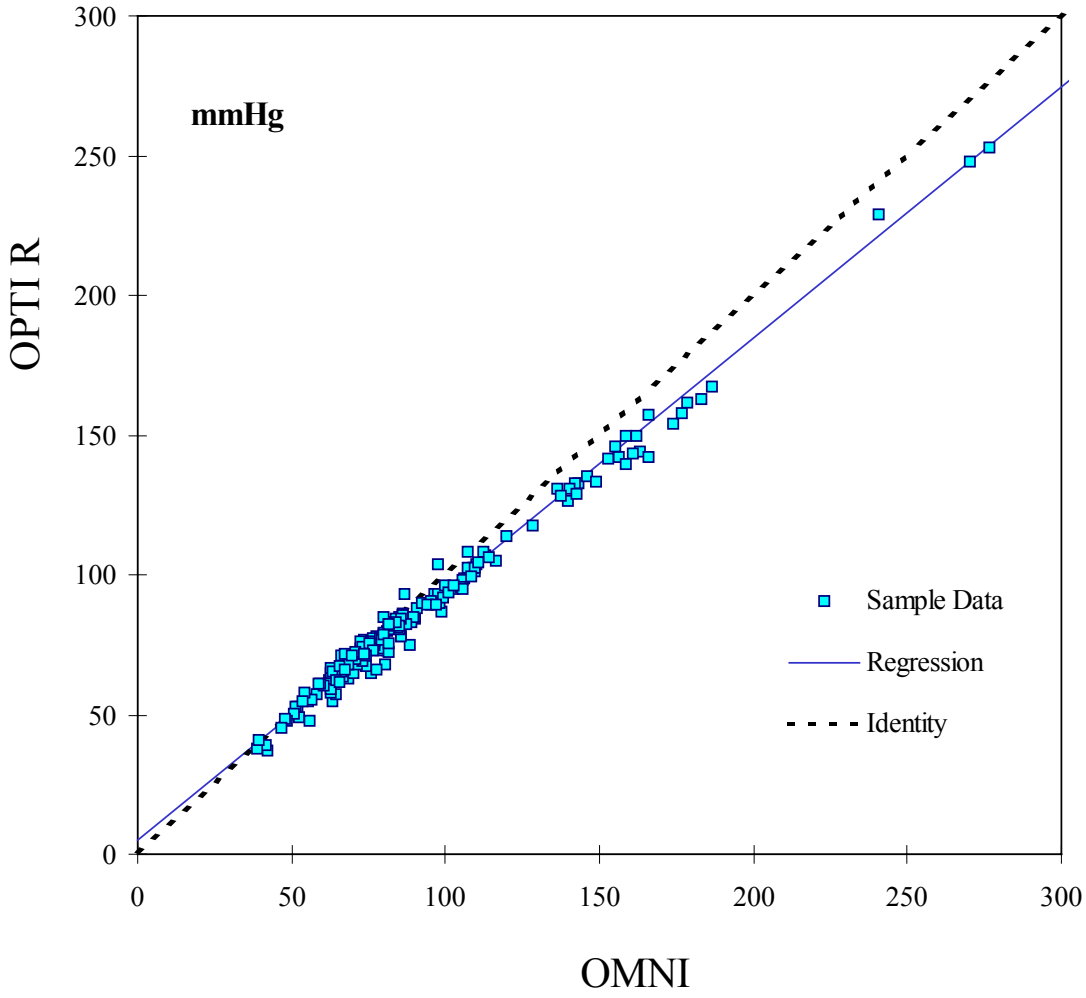
Correlation

number of pairs (n):	178
slope (m):	1.05124
y-intercept (b):	-3.19544
y-intercept (normalized):	-1.1457
regression coefficient (r^2):	0.98330
correlation coefficient (r):	0.99161
std error of y estimate:	1.7984
average difference:	-0.874
SD of differences:	1.91
P(T<=t) two-tail:	0.54

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. OMNI
PO2



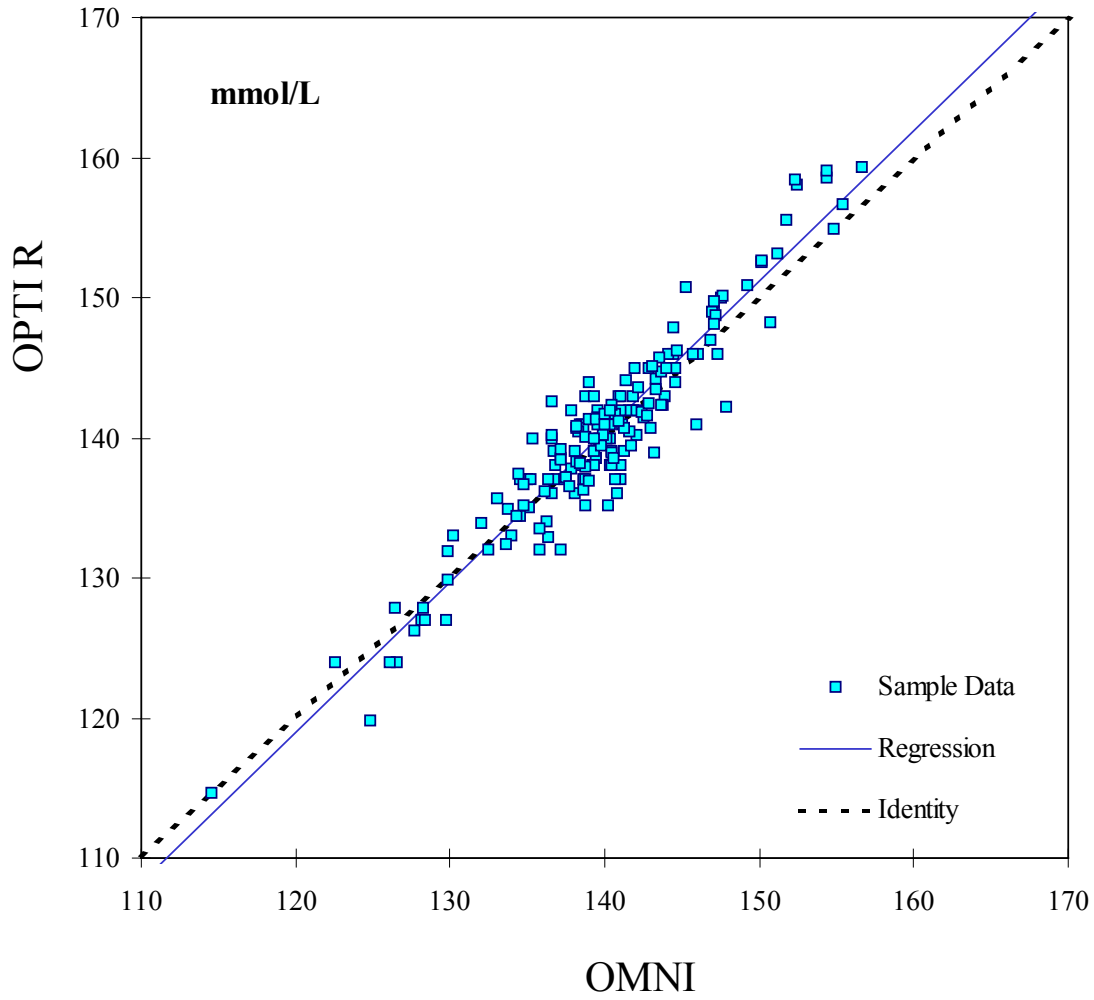
Correlation

number of pairs (n):	178
slope (m):	0.8984
y-intercept (b):	4.9257
y-intercept (normalized):	-4.2219
regression coefficient (r^2):	0.99343
correlation coefficient (r):	0.99671
std error of y estimate:	3.7942
average difference:	-5.034
SD of differences:	6.48

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. OMNI
Na+



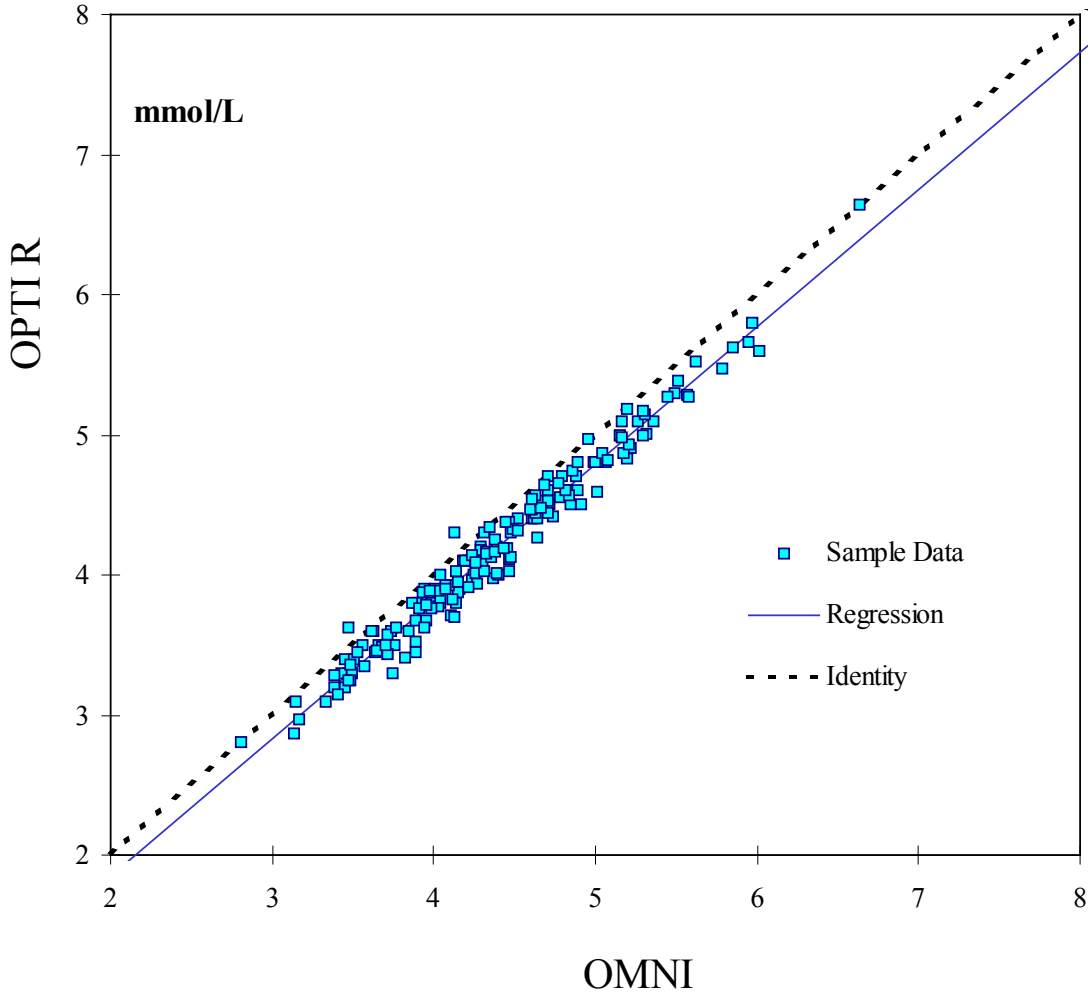
Correlation

number of pairs (n):	178
slope (m):	1.07284
y-intercept (b):	-9.804
y-intercept (normalized):	0.3937
regression coefficient (r^2):	0.89572
correlation coefficient (r):	0.94642
std error of y estimate:	2.2593
average difference:	0.383
SD of differences:	2.297
P(T<=t) two-tail:	0.58

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. OMNI
K+



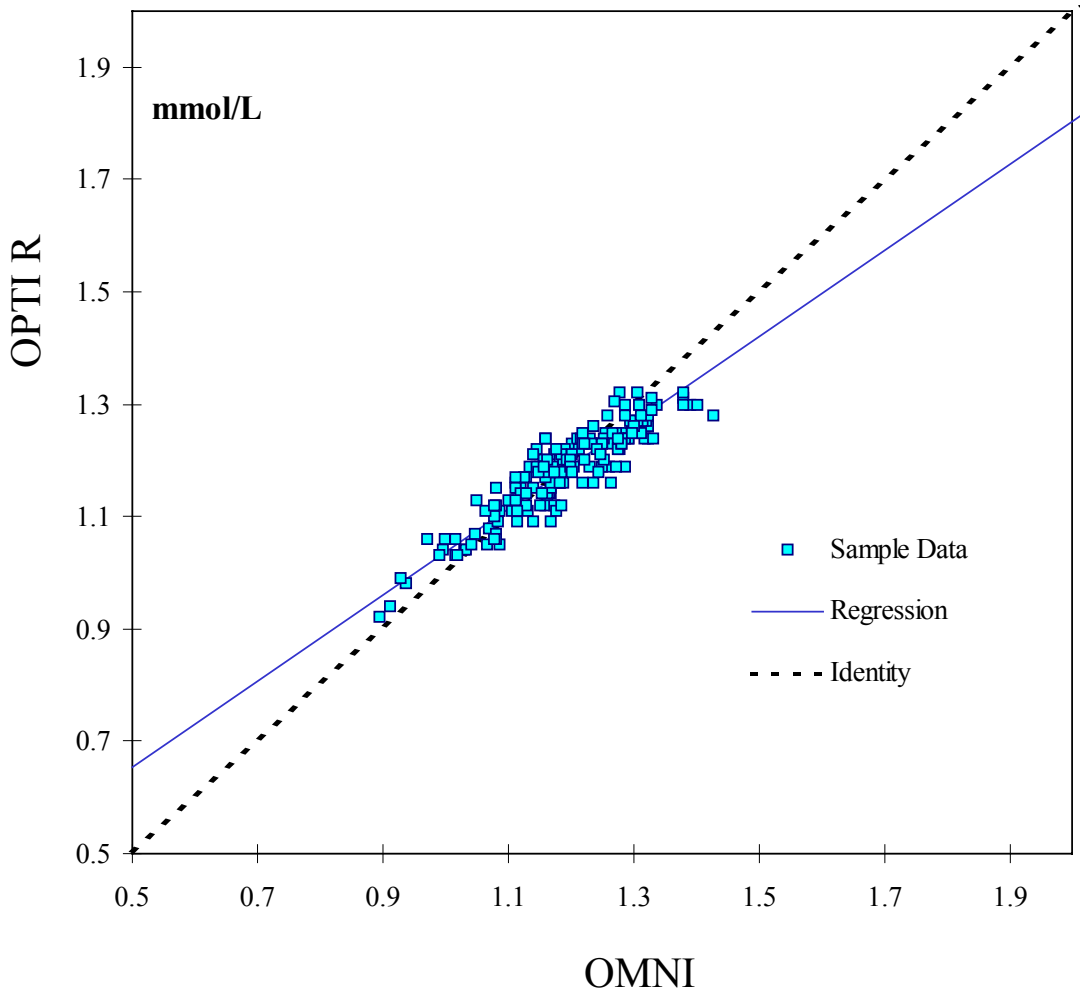
Correlation

number of pairs (n):	178
slope (m):	0.9789
y-intercept (b):	-0.103
y-intercept (normalized):	-0.1869
regression coefficient (r^2):	0.97406
correlation coefficient (r):	0.98694
std error of y estimate:	0.1097
average difference:	-0.195
SD of differences:	0.110
P(T<=t) two-tail:	0.01

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. OMNI
iCa++



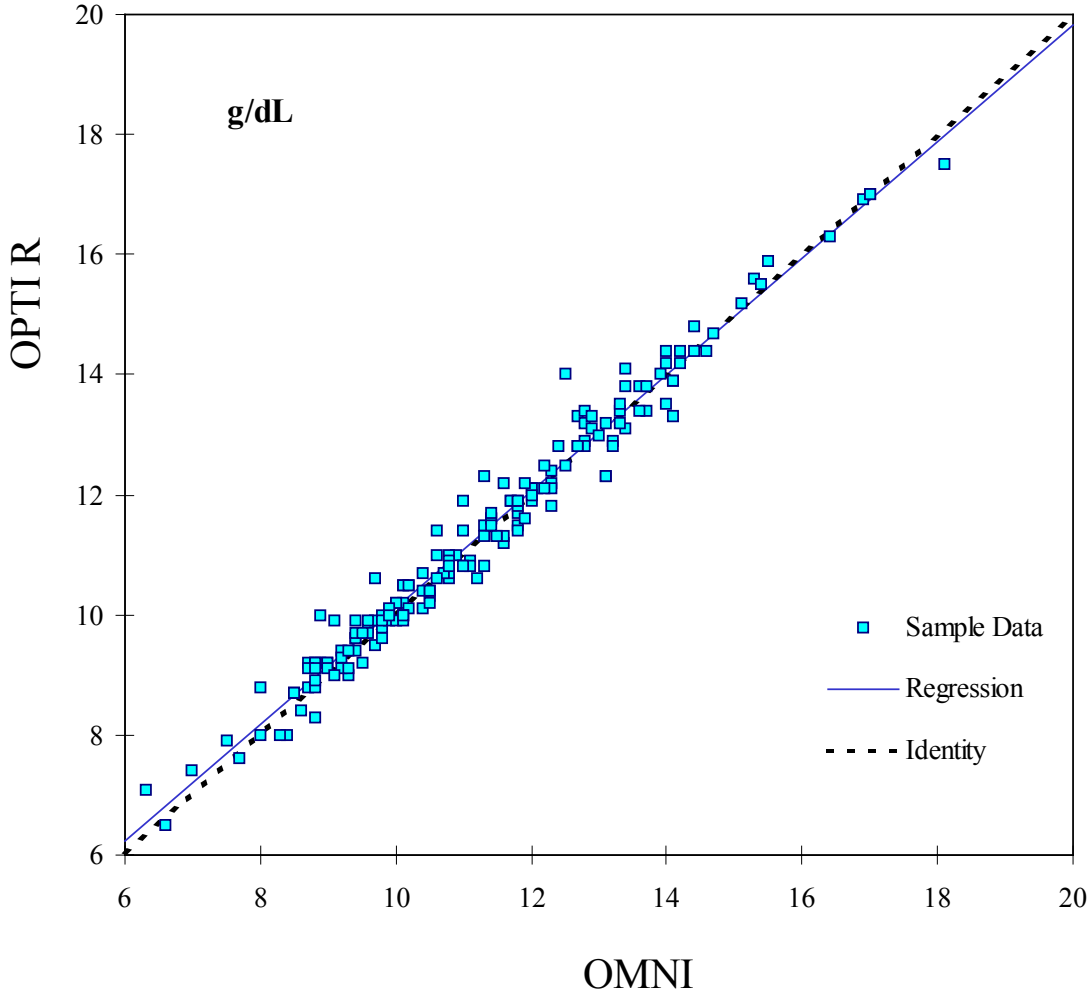
Correlation

number of pairs (n):	178
slope (m):	0.7661
y-intercept (b):	0.270
y-intercept (normalized):	0.0124
regression coefficient (r^2):	0.86734
correlation coefficient (r):	0.93131
std error of y estimate:	0.0343
average difference:	-0.008
SD of differences:	0.043
P(T<=t) two-tail:	0.47

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. OMNI
ctHb



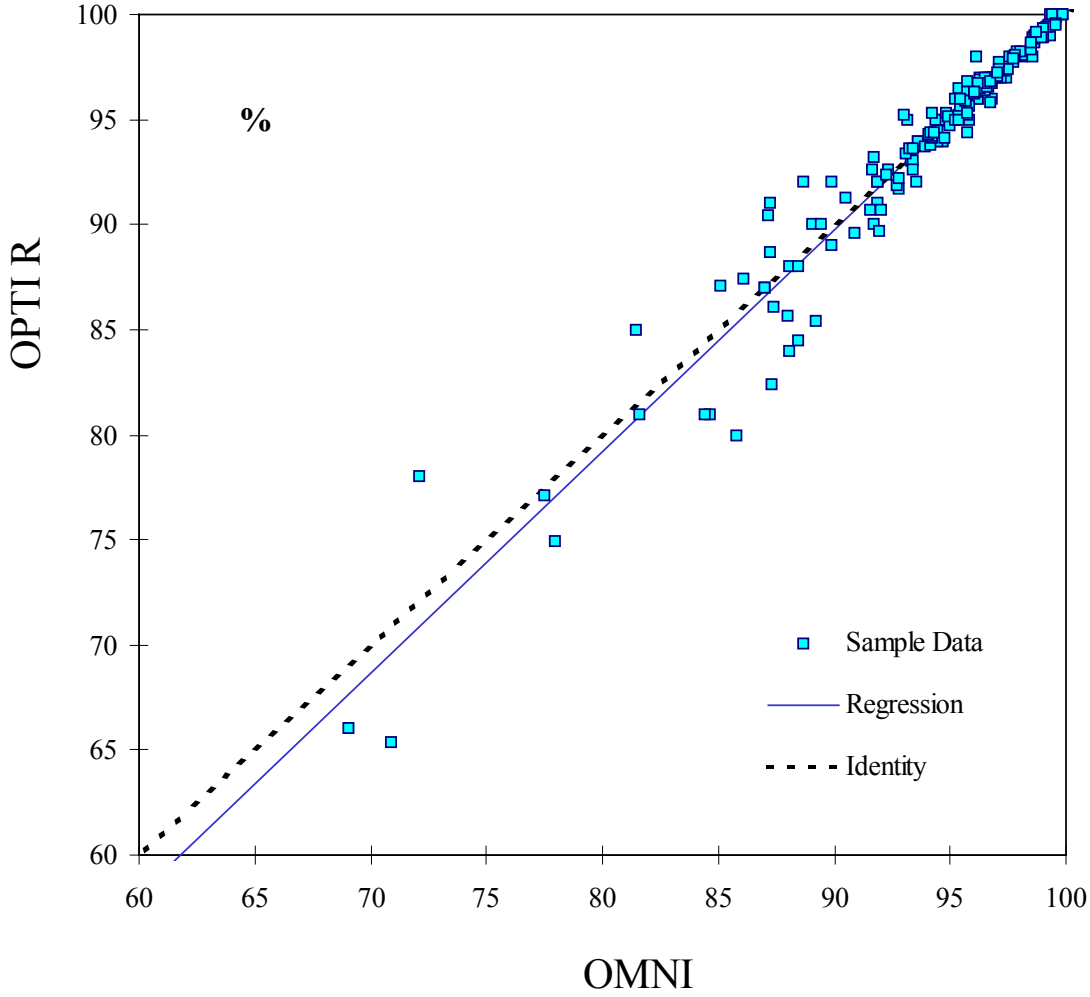
Correlation

number of pairs (n):	178
slope (m):	0.97057
y-intercept (b):	0.4077
y-intercept (normalized):	0.0250
regression coefficient (r^2):	0.97456
correlation coefficient (r):	0.98720
std error of y estimate:	0.3373
average difference:	0.077
SD of differences:	0.342
P(T<=t) two-tail:	0.73

OPTI R Analyzer

Correlation to Predicate Methods

OPTI R vs. Calculated SO2
SO2 vs SO2c



Correlation

number of pairs (n):	178
slope (m):	1.05462
y-intercept (b):	-5.1927
y-intercept (normalized):	-0.277
regression coefficient (r^2):	0.944
correlation coefficient (r):	0.971
std error of y estimate:	1.354
average difference:	178.000
SD of differences:	-0.052
P(T<=t) two-tail:	0.93

8.2 Conducting A Field Test (Correlation)

As always the first concern before utilizing patient samples for a study is to provide accurate and acceptable results to be reported to the facility. After which the results and/or the remnant samples may be used for conducting this study.

8.2.1 Using Results from the Reported Measurement:

- To ensure the most accurate and best correlation between the two devices, always mix the sample well for approx. 15 seconds by rolling between the palms of your hands and inverting end-over-end before placing on the predicate device.
- After measuring the sample on the predicate device expel any air from the sample syringe and cap this sample for later measurement on the OPIT Analyzer. Only after the results have been reported and accepted should this sample be used for correlation purposes. This will ensure adequate sample material to provide the patient results to the facility.
- If not immediately performing the second measurement place these capped samples on ice. Samples may be kept on ice for up to 1 hour.
- Before mixing the sample on the OPTI Analyzer **mix the sample well for approx. 15 seconds by rolling between the palms of your hands and inverting end-over-end.** This will ensure an accurate tHb/SO2 measurement on the OPTI Analyzer. **DO NOT PLACE THE SAMPLE ON THE OPTI UNTIL YOU ARE PROMPTED.**
- Compare the results between the predicate device and the OPTI.

NOTE: To ensure the most accurate results and best correlation, always mix the sample well prior to measuring on the predicate device.

8.2.2 Conducting an Independent Correlation Evaluation (Preferred Method)

This is the preferred method of comparison since it can provide the largest span of blood sample measurement ranges for your data set. However additional sample (blood) material may be required.

- After measuring the sample on the predicate device expel any air from the sample syringe and cap this sample for later measurement. Only after the results have been accepted and reported should this remnant sample be saved for later use.
- Place these capped samples on the side for later evaluation. These remnant samples are now considered waste and can be used for the evaluation purposes.
- When the desired amount of samples has been collected the remnant samples can then be utilized for the evaluation purposes.
- Mix each sample by rolling between the palms of your hands and inverting end-over-end for approx. 15 seconds.
- Place the sample to be analyzed on the predicate device and perform the measurement as usual. Remove the sample and expel any air in the sample.

- Again, mix each sample by rolling between the palms of your hands and inverting end-over-end for approx. 15 seconds.
- Place the sample to be analyzed on the OPTI and perform the measurement as usual.
- Compare the results between the predicate device and the OPTI.

Since the samples are remnant, and only needed for this correlation they may be modified to achieve varying ranges of the measured parameters. An example is shown below.

High tHb Stand syringe on end and let the plasma rise to the needle end. Eject this plasma and measure to achieve high values of tHb.

Low tHb Stand syringe on end and let the red cells fall to the needle end. Eject these cells and use plasma to taint other samples. Thus providing lower tHb values.

The remnant samples may be mixed with salt, exposed to room air or other varying techniques to gain a wider range of measured values. This will lead to an overall better correlation.

8.2.3 Special Thoughts and Considerations

- Sample should be collected in a larger than 1cc syringe
- Lithium heparin is the recommended when conducting correlation's of this type
- It is recommended to compress the time between sample measurements as much as possible. This is extremely important when using the results from the reported measurement.
- Never run the OPTI Analyzer first when conducting a correlation since the OPTI aspirates the sample and will then contaminate the remaining sample material. This is true with any instrument that automatically aspirates the sample for analysis.
- If the predicate device automatically aspirates the sample the OPTI measurement will then vary from the predicate device

9 SERVICE CONCEPT – Roche OPTI R ANALYZER

9.1 Service Aspects

Please find below a short description of the OPTI R Analyzer service concept. For further detailed information, please contact the responsible Global System Support in Graz or Roswell.

9.1.1 General

The customer should be able to solve the following problems, with assistance by phone:

- Recognize operator errors
- Eliminate contamination (cleaning of the instrument)
- Check of the instrument performance by using controls
- Report cause of error to service team by phone or letter

9.1.2 Instrument Repair

Prior to returning the OPTI R Analyzer for repair the instrument functionality should be assessed utilizing the onboard diagnostic routines. Additionally, when possible three levels of OPTI-check liquid quality control material should be run. For further information an error log may also be printed to provide assistance in troubleshooting the analyzer prior to shipment back to the site of manufacturing.

Just in case that OPTI R Analyzer can`t be repaired locally, please send the defective OPTI R instruments to the respective repair centre in Graz or Roswell by using the RA-procedure.

Please answer all the questions on the RA form with the greatest care and sign the form.

- Country code
- Problem date
- Type of instrument
- Serial number of instrument
- Installation date of instrument
- Defective instrument or spare part
- Part number and material number of the spare part
- Old / new serial number
- Fault description etc.

All returned instruments/parts should be individually labeled with the corresponding RA number and shipped together with the completed RA form to the respective repair centre.

Roche Diagnostics Corporation
235 Hembree Park Drive
Roswell, Georgia 30076-1447
USA

Roche Diagnostics GmbH
Hans-List-Platz 1
A-8020 Graz
Austria

9.1.3 Local Instrument Repair / Service Training

The Global System Supports in Graz and Roswell are offering service trainings according to the training schedules which can be found in the INTRANET in the near future.

Trainings are organized according to the "train the trainer" concept.

Successful participation is documented with a certificate, which authorizes trainings of technical service staff locally. Depending on your needs and economical reasons as well (traveling costs, number of participants, etc.) a training class can be held in Roswell or other locations as deemed necessary.

9.1.4 Service Manual

Technical information is provided in the OPTI R Service Manual, **English**, which is available under Roche Reference Number 03077039001.